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SOLICITATION, OFFER AND AWARD

1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)	RATING	PAGE 1 OF PAGES 156

2. CONTRACT NO.	3. SOLICITATION NO.	4. TYPE OF SOLICITATION	5. DATE ISSUED	6. REQUISITION/PURCHASE NO.
N/A	**RFP-13-100-SOL-00008**	☐ SEALED BID (IFB) ☒ NEGOTIATED	**04/01/2013**	N/A

7. ISSUED BY	CODE	8. ADDRESS OFFER TO *(If other than Item 7)*
HHS/OS/ASPR/AMCG 330 Independence Ave, SW, RM G-640 Washington, DC 20201		

NOTE: In sealed bid solicitations "offer" and "Offeror" mean "bid" and "bidder."

SOLICITATION

9. Sealed offers in original and **0** copies for furnishing the supplies or services in the Schedule will be received at the place specified in Item 8, or if handcarried, in the depository located in See Block 7 until **12:00 PM** *(Hour)* local time **May 16, 2013** *(Date)*

CAUTION -- LATE Submissions, Modifications, and Withdrawals: See Section L, Provision No. 52.214-7 or 52.215-1. All offers are subject to all terms and conditions contained in this solicitation.

10. FOR INFORMATION CALL:	A. NAME	a. TELEPHONE *(NO COLLECT CALLS)*	b. E-MAIL ADDRESS
	Matthew McCord	(202) 260-0689	**matthew.mccord@hhs.gov**

11. TABLE OF CONTENTS

((x))	SEC.	DESCRIPTION	PAGE(S)	(x)	SEC.	DESCRIPTION	PAGE(S)
PART I – THE SCHEDULE				PART II – CONTRACT CLAUSES			
X	A	SOLICITATION/CONTRACT FORM	01	X	I	CONTRACT CLAUSES	41
X	B	SUPPLIES OR SERVICES AND PRICES/COSTS	03	PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACH.			
X	C	DESCRIPTION/SPECS./WORK STATEMENT	09	X	J	LIST OF ATTACHMENTS	52
X	D	PACKAGING AND MARKING	17	PART IV – REPRESENTATIONS AND INSTRUCTIONS			
X	E	INSPECTION AND ACCEPTANCE	18		K	REPRESENTATIONS, CERTIFICATIONS, AND	
X	F	DELIVERIES OR PERFORMANCE	19	X		OTHER STATEMENTS OF OFFERORS	53
X	G	CONTRACT ADMINISTRATION DATA	25	X	L	INSTRS., CONDS., AND NOTICES TO OFFERORS	56
X	H	SPECIAL CONTRACT REQUIREMENTS	30	X	M	EVALUATION FACTORS FOR AWARD	70

OFFER *(Must be fully completed by Offeror)*

NOTE: Item 12 does not apply if the solicitation includes the provisions at 52.214-16, Minimum Bid Acceptance Period.

12. In compliance with the above, the undersigned agrees, if this offer is accepted within _____ calendar days *(60 calendar days unless a different period is inserted by the Offeror)* from the date for receipt of offers specified above, to furnish any or all items upon which prices are offered at the price set opposite each item, delivered at the designated point(s), within the time specified in the schedule.

13. DISCOUNT FOR PROMPT PAYMENT *(See Section I, Clause No. 52-232-8)*	10 CALENDAR DAYS %	20 CALENDAR DAYS %	30 CALENDAR DAYS %	CALENDAR DAYS

14. ACKNOWLEDGMENT OF AMENDMENTS *(The Offeror acknowledges receipt of amendments to the SOLICITATION for Offerors and related documents numbered and dated:*	AMENDMENT NO.	DATE	AMENDMENT NO.	DATE

15A. NAME AND ADDRESS OF OFFEROR	CODE	FACILITY	16. NAME AND ADDRESS OF PERSON AUTHORIZED TO SIGN OFFER *(Type or Print)*

15B. TELEPHONE NO. AREA CODE NUMBER EXT.	☐ 15C. CHECK IF REMITTANCE ADDRESS IS DIFFERENT FROM ABOVE - ENTER SUCH ADDRESS IN SCHEDULE.	17. SIGNATURE	18. OFFER DATE

AWARD *(To be completed by Government)*

19. ACCEPTED AS TO ITEMS NUMBERED	20. AMOUNT	21. ACCOUNTING AND APPROPRIATION

22. AUTHORITY FOR USING OTHER THAN FULL AND OPEN COMPETITION: ☐ 10 U.S.C. 2304(c)( ) ☐ 41 U.S.C. 253(c)( )	23. SUBMIT INVOICES TO ADDRESS SHOWN IN *(4 copies unless otherwise specified)*	ITEM

24. ADMINISTERED BY *(If other than Item 7)* CODE	25. PAYMENT WILL BE MADE BY CODE

26. NAME OF CONTRACTING OFFICER *(Type or print)*	27. UNITED STATES OF AMERICA *(Signature of Contracting Officer)*	28. AWARD DATE

IMPORTANT -- Award will be made on this form, or on Standard Form 26, or by other authorized official written notice.

NOTE TO OFFERORS

The information in SECTION A - Solicitation/Contract Form, contains important information for any Offeror interested in responding to this solicitation. Any contract resulting from this solicitation will include in its SECTION A - Solicitation/ Contract Form, accounting, appropriation and general information applicable to the contract award.

The contract schedule, set forth in Sections B through H, contains contractual information pertinent to this solicitation. It is not an exact representation of the contract document that will be awarded as a result of this solicitation. The contract cost or price and other contractual provisions unique to the Offeror's proposal may be included in the resultant contract.

The contract schedule is intended to provide the Offeror with information to aid in understanding the likely terms and conditions of any resultant contract.

PART I – THE SCHEDULE

SECTION B – SUPPLIES OR SERVICE AND PRICE / COST

MEDICAL COUNTERMEASURES CLINICAL STUDIES NETWORK

B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES

This Request for Proposals (RFP) solicits proposals for an indefinite delivery, indefinite quantity (IDIQ) contracts for the execution of clinical services. It is anticipated that fixed price or cost type task orders will be issued under this contract.

The Biomedical Advanced Research and Development Authority (BARDA) within the Office of the Assistant Secretary for Preparedness and Response (ASPR) at the U.S. Department of Health and Human Services (HHS), seeks to establish a Medical Countermeasure Clinical Studies Network (MCM CSN) to facilitate Medical Countermeasure (MCM) product development towards licensure. BARDA has a specific need to create a clinical core service to support clinical development of the product candidates in its development pipeline. BARDA needs clinical core services because BARDA-sponsored product developers and manufacturers may not have the appropriate or adequate clinical expertise, may not be interested in pursuing an indication relevant to the mission of BARDA, or may be cost-prohibited to pursue. Additionally, during a public health medical emergency, additional clinical services beyond present government capacities may be needed to provide supportive regulatory data for the use of these products (e.g., post-licensure field effectiveness studies). Through a set of contractual agreements, BARDA will establish a network of Clinical Research Organizations (CROs) to provide a wide-array of clinical services to meet BARDA requirements. The activities and clinical sites of the BARDA MCM CSN will be coordinated with clinical studies performed by HHS interagency and industry partners, especially with those of the National Institute of Allergy and Infectious Diseases (NIAID). BARDA will coordinate the activities and management of the MCM CSN.

The Pandemic and All Hazards Preparedness Act (PAHPA) of 2006 established the Biomedical Advanced Research and Development Authority (BARDA) to support development and acquisition of medical countermeasures (MCMs) to prevent or treat the medical consequences of chemical, biological, radiological, and nuclear (CBRN) threats, pandemic influenza (PI), and emerging infectious diseases (EID). These MCMs include vaccines, therapeutics, diagnostics, and medical devices. Additionally, BARDA is entrusted to foster innovation of technologies that enable better manufacturing, testing, and utilization of these medical countermeasures.

This network will complement the academic and research focused network of clinical sites established by NIAID using a CRO-based clinical network for product evaluations rather than an academic institution-based model. Clinical samples from BARDA MCM CSN clinical studies will be made available to the NIAID as requested to compare and further analyze immunological and other host responses to the product(s) and to provide further knowledge on the mode of action or identification of surrogates/correlates. The provision of samples will be closely coordinated and established by BARDA and NIAID with industry partners and CROs during clinical protocol development.

As directed by Task Order(s), MCM CSN contractors shall provide clinical services in support of the execution of adequate and well controlled Food and Drug Administration (FDA) regulated trials, either Phase 1 – 4, or trials during a public health medical emergency. Clinical services will support the evaluation of Chemical, Biological, Radiological, Nuclear (CBRN), Pandemic Influenza (PI), and Emerging Infectious Disease (EID) medical countermeasures. Studies may include healthy adults, pediatric, elderly and other populations with special medical requirements. Study timelines will be specified in the Task Order (e.g. routine or urgent). MCM CSN contractors will perform targeted clinical studies relevant to BARDA's vision to create a nation with the capability to respond quickly and effectively to deliberate, natural and emerging threats by providing a range of clinical study services that can be used by BARDA and development partners of BARDA.

B.2. SPECIFIC REQUIREMENTS

Objective 1: Clinical Studies: Clinical services shall support the evaluation of CBRN, PI and/or EID MCMs.
Objective 2: Clinical Trial Response Readiness: Task Orders may require the development and implementation of a detailed plan to permit the initiation of a clinical study within a predefined timeframe.

B.3. CONTRACT TYPE

The Government intends to award one or more indefinite-delivery, indefinite-quantity (IDIQ) contract(s) for clinical study services. During the period of performance of the contract, the government may order, and the Contractor shall provide, services as identified in future Task Orders. At the discretion of the government, Task Orders issued under this contract may be Firm-Fixed Price (FFP) or Cost Reimbursement (CR).

B.4. PRICES / COSTS

The final contract will contain the price/cost provisions agreed upon by the Government and the Offeror.

It is anticipated that any contract awarded under this solicitation shall contain a base period of two years (24 months). It is further anticipated that any resulting contract will include three consecutive one year (12 months) contract options. Contract options are exercised at the discretion of the government. Exercise of these options could increase the total period of performance to five years (60 months).

The Government will issue Requests for Task Order Responses (RTORs) and contractors will compete for Task Orders for clinical research services based on the work described in the Statement of Objectives in SECTION C of this contract. Upon delivery and acceptance of the services described in each Task Order, the Government shall pay to the Contractor the price, costs or fee set forth in the Task Order.

Below is a possible Contract Line Item Number (CLIN); the final contract will contain CLINs agreed upon by the Government and the Offeror. Offerors are invited to propose alternate CLINs and sub-CLINs.

B.4.1. Base Period

CLIN #	Description of Option Item(s) -or- Option Service(s)	Estimated Cost or Price
0001	Base Period (24 months) – Clinical Study Services and Technical Reports on Task Orders.	TBD*

** Business proposals shall include labor rate costs, facility costs, and all other costs necessary to complete clinical study services*

B.4.2. Option Periods

The final contract will contain the price/cost provisions for Options agreed upon by the Government and the Offeror.

Below is a list of possible Optional CLINs; the final contract will contain Optional CLINs agreed upon by the Government and the Offeror:

CLIN #	Description of Option Item(s) -or- Option Service(s)	Estimated Cost or Price
0002	Option Year One – Clinical Study Services and Technical Reports on Task Orders.	TBD*
0003	Option Year Two – Clinical Study Services and Technical Reports on Task Orders.	TBD*
0004	Option Year Three – Clinical Study Services and Technical Reports on Task Orders.	TBD*

** Business proposals shall include labor rate costs, facility costs, and all other costs necessary to complete clinical study services*

Unless the Government exercises its option pursuant to the option clause referenced in SECTION I.3. Additional Contract Clauses, this contract consists only of the base award.

B.4.2.1. Option Year One

The USG may exercise optional CLIN 0002 to extend the contract for clinical study services for 12 months beyond the base award term.

B.4.2.2. Option Year Two

The USG may exercise optional CLIN 0003 to extend the contract for clinical study services for 12 months beyond Option Year One.

B.4.2.3. Option Year Three

The USG may exercise optional CLIN 0004 to extend the contract for clinical study services for 12 months beyond Option Year Two.

B.5. ADVANCE UNDERSTANDINGS

The final contract may contain additional advance understandings between the Government and the Offeror.

B.5.1. Minimum Ordering Amount

The Contractor or Contractors shall each be reimbursed by the Government in an amount not less than a total of **$400,000.00** for all contract Task Orders awarded during the base period under this solicitation. The Government is not obligated to order more than the stated minimum for the base contract period.

Each of the possible Optional CLINs, if exercised, would obligate the government for an additional **$200,000.00** per Contractor.

B.5.2. Maximum Ordering Amount – $600,000,000.00

The Contractor(s) shall not receive payment from the Government in an amount greater than **$600,000,000.00** for successful performance under this contract. This contract ceiling is the Government's most optimistic scenario with respect to the Government's needs and level of funding.

B.5.3. Fulfilling Minimum Order Requirements

The minimum guarantee under this IDIQ contract is $400,000.00 per contractor. This amount can only be claimed at the end of the period of performance of the base contract if the Contractor takes advantages of fair opportunity, as described in FAR 16.505, by proposing on at least one Task Order.

If the Government fails to award Task Orders to each contractor in the amount of $200,000.00 during any option period of performance after exercising any of the possible Optional CLINs as described in SECTION B.4, the affected Contractor(s) may invoice for the balance of this additional guaranteed minimum. This amount can only be claimed at the end of the period of performance of the corresponding option contract if the Contractor takes advantages of fair opportunity, as described in FAR 16.505, by proposing on at least one Task Order during that period.

B.5.4. Pricing of Task Orders

Individual Task Orders will be issued as requirements occur, and will specify work to be performed. The Contractor shall perform all services in accordance with each task order's work statement/specifications. The terms and conditions set forth in this contract will always apply.

See SECTION G.4. for further ordering information and procedures.

B.5.5. Funding

Funds for the services provided will be obligated, at the task order level, as they become available, or excess funds de-obligated at the task order level, by modification to the task order contracts unilaterally by the Government. The contractor will only be paid for effort that has been authorized by the Government and performed in accordance with the contract specifications, except for the minimum amount guaranteed.

B.5.6. Cost Unallowable Unless Authorized by the Contracting Officer

This section prohibits or restricts the use of contract funds for the following, unless otherwise approved in advance by the Contracting Officer:

a) Acquisition, by purchase or lease, of any interest in real property;
b) Rearrangement or alteration of facilities;
c) Purchase of lease of any item of general purpose office furniture or office equipment regardless of dollar value;
d) Accountable Government Property;
e) Travel to attend general scientific meetings/conferences;
f) Foreign Travel Costs;
g) Costs incurred in the performance of any cost-reimbursement type subcontract (including consulting agreements);
h) Costs to be paid for the performance of a fixed-price subcontract that exceeds $150,000.00;
i) Patient Care Costs; and
j) Light Refreshment and Meal Expenditures - Requests to use contract funds to provide light refreshments and/or meals to either federal or nonfederal employees must be submitted to the Contracting Officer's Representative (COR), with a copy to the Contracting Officer, at least six (6) weeks in advance of the event and are subject to "HHS Policy on Promoting Efficient Spending: Use of Appropriate Funding for Conferences and Meetings, Food and Promotional Items and Printing and Publications." The request shall contain the following information: (a) name, date, and location of the event at which the light refreshments and/or meals will be provide; (b) a brief description of the purpose of the event; (c) a cost breakdown of the estimated light refreshments and/or meals costs; (d) the number of nonfederal and federal attendees receiving light refreshments and/or meals; and (e) if the event will be held at a government facility.

B.5.7. Invoices - Cost and Personnel Reporting, and Variances from the Negotiated Budget

For contract work performed on a cost reimbursement basis, the Contractor agrees to provide a detailed breakdown on invoices of the following cost categories (as applicable):

1. Direct Labor - Include salaries and wages paid (or accrued) for direct performance of the contract. List individuals by name, title/position, hourly/annual rate, level of effort (actual hours or % of effort), breakdown by task performed by personnel, and amount claimed.
2. Fringe Benefits - Cite rate and amount

3. Overhead - Cite rate and amount
4. Materials & Supplies - Include detailed breakdown when unit price is over $1,000.
5. Travel - Identify travelers, dates, destination, purpose of trip, and amount. Cite COA, if appropriate. List separately, domestic travel, general scientific meeting travel, and foreign travel.
6. Consultant Fees - Identify individuals and amounts.
7. Subcontracts - Attach subcontractor invoice(s).
8. Equipment - Cite authorization and amount.
9. G&A - Cite rate and amount.
10. Total Cost
11. Fixed Fee
12. Total Cost Plus Fixed Fee (Total CPFF)

For contract work performed on a cost reimbursement basis, monthly invoices must include the cumulative total expenses to date, adjusted (as applicable) to show any amounts suspended by the Government. Also note the Contracting Officer may require the Contractor to submit detailed support for costs claimed on payment requests. Every cost must be determined to be allocable, reasonable, and allowable per FAR Part 31.

SECTION C – STATEMENT OF OBJECTIVES (SOO)

C.1. INTRODUCTION/BACKROUND

This acquisition is part of a comprehensive strategy and commitment in the BARDA Strategic Plan (2011) to establish core service assistance to MCM developers directly in the form of technical, clinical and regulatory assistance, and assist BARDA in addressing public health needs in an emergency. To date, BARDA has provided core service assistance to developers directly in the form of technical, clinical, and regulatory assistance from internal subject matter experts. BARDA has partnered with more than 12 laboratories comprising an animal studies network to provide CBRN MCM developers with animal model development and current Good Laboratory Practice (cGLP) animal challenge studies. BARDA has utilized the animal studies network to evaluate lead product candidates to determine whether additional development and investment into these product candidates were warranted. Further BARDA core services include the Centers for Innovation in Advanced Development and Manufacturing (CIADM) established by BARDA in 2012 with industry and government partners to assist biological product developers with development and manufacturing assistance. The CIADMs were created to manufacture rapidly vaccines and other biological products in emergencies including influenza pandemics or emerging infectious disease outbreaks.

BARDA also wishes to provide core service assistance to MCM developers in the clinical evaluation of MCMs towards product licensure such as those product developers utilizing the services of the BARDA-supported Centers for Innovation in Advanced Development and Manufacturing. Additionally, there is need for clinical studies by BARDA during public health emergencies, when collection of clinical information about a MCM is necessary for its utilization during that emergency or to fulfill post-licensure marketing commitments with industry partners during an event. This core service will assist in the clinical development of MCMs addressing the public health and medical consequences of CBRN accidents, incidents and attacks, PI, and EID. This core service supports the Office of the ASPR's objective to lead the country in preparing for, responding to, and recovering from the adverse health effects of emergencies and disasters.

The strategic objectives of this acquisition are to:

- Provide a clinical study core service for use on a routine or emergency basis by BARDA and by BARDA's product development partners
- Enhance BARDA's preparedness and response to CBRN, PI and EID threats.
- Promptly complete clinical activities supporting regulatory applications including but not limited to EUA.
- Conduct urgently needed clinical trials during a public health emergency.
- Improve financial management of clinical trials and potentially reduce the MCM clinical development costs to BARDA.
- Reduce the risk associated with less mature or repurposed products by expanding the available clinical data.

This acquisition provides the clinical services needed for BARDA to establish a network of clinical research organizations. BARDA MCM Programs will identify their clinical service needs, and BARDA will review and prioritize these clinical service requests. The prioritized list of clinical service requests will be presented to an HHS interagency coordination committee, which will include representatives from the Centers for Disease Control and Prevention (CDC), the Food and Drug

Administration (FDA), NIAID, and BARDA to identify clinical service resources that may be available. If the determination is made that the BARDA clinical services network best addresses the BARDA program's clinical service request, then BARDA will issue a task order for competitive bid among members of the BARDA clinical services network, in accordance with FAR 16 for "Indefinite delivery – indefinite quantity (ID-IQ) contracts."

Request for Task Order Response (RTOR) proposals from BARDA clinical service network members will be evaluated and awarded in accordance with FAR 16.505.

MCM safety and efficacy data in healthy adult, pediatric, elderly, immune-compromised and other special populations are critical for the use of these products in these populations. Once the regulatory path for these populations has been defined, the BARDA clinical services network is expected to address BARDA's clinical study needs in these groups in normal development but especially during public health emergencies. The BARDA clinical services network will allow collection of data for special populations or product uses that are not in the approved package insert or business plan of the company developing the product, when other means are not available.

The studies executed by the BARDA clinical services network are expected to provide data packages supportive of Emergency Use Authorization (EUA) for BARDA MCMs. The BARDA clinical services network will also allow the collection of efficacy data during a declared emergency and EUA product use and assist industry partners in the planning and execution of post-licensure safety and effectiveness studies during public health emergencies using BARDA-supported MCMs (e.g., pandemic influenza vaccines).

C.2. REFERENCES

Pandemic All-Hazard Preparedness Act of 2006 (PL109-417)

Pandemic and All-Hazards Preparedness Reauthorization Act of 2012 (PL113-5)

BARDA Strategic Plan 2011-2016 (Washington DC: U.S. Department of Health and Human Services Assistant Secretary for Preparedness and Response, October 14, 2011), http://www.phe.gov/about/barda/Documents/barda-strategic-plan.pdf

ASPR Strategic Plan 2011-2015, accessed February 29, 2012. http://www.phe.gov/about/aspr/strategic-plan.

C.3. SCOPE AND TECHNICAL REQUIREMENTS

Independently and not as an agent of the US Government (USG), the Contractor shall furnish all the necessary services, qualified personnel, materials, supplies, equipment and facilities not otherwise provided by the USG as needed to perform the work described.

C.3.1. Objective 1: Clinical Studies

The Offeror shall provide clinical research services and study execution as a service to BARDA. These studies will clinically evaluate CBRN, PI and/or EID MCMs. These studies may be Phase 1, 2, 3, or 4 (as defined by the FDA) or combinations of these phases.

Clinical research services may include the following components:

1. Planning and pre-study activities
    a. Protocol development support services, including the development of clinical protocols and protocol-related documents
    b. Assist BARDA/DCS in final study protocol and investigator brochure development
    c. Regulatory and other document preparation, editing, formatting, submission and approval(s)
    d. Protocol specific clinical site monitoring, identification, assessments and selection plans
    e. Establishment of sub-contracts necessary to execute the study
    f. Development and implementation of training programs for clinical site personnel regarding the conduct of clinical trials including Quality Management
2. Safety monitoring
    a. Provision of 24 hour medical monitoring
    b. Develop, initiate, and maintain an appropriate safety review committee (SRC) or independent data safety and monitoring board (DSMB)
    c. Develop and institute plans for safety assessment and monitoring activity including identification, reporting and tracking systems for AEs, SAEs, as well as an effective medical monitoring action plan which includes stopping rules and communications of adverse events to all clinical sites
3. Document creation and management
    a. Receipt, assessment and maintenance of essential site regulatory documentation
    b. Creation and maintenance of clinical trial master file(s)
    c. Provide clinical site regulatory support including preparing, submitting and maintaining regulatory documents
    d. Assistance in the preparation of study-related materials and instructions
    e. Medical writing including but not limited to final clinical study reports
    f. Assist BARDA in obtaining necessary regulatory documents and approvals, developing CRFs, investigational drug brochures and clinical trial master file(s)
4. Clinical trial execution
    a. Performing clinical site initiation visits

   b. Execution of the clinical protocol including assisting sites with the development of subject recruitment plans, subject retention strategies and monitoring enrollment
   c. Planning and conducting clinical site monitoring and reporting
   d. Development and implementation of clinical site quality management programs
   e. Site essential document management activities
   f. Enrollment, site visits, SAEs, etc
   g. Training of clinical site staff and assessment of clinical site capabilities for data collection and management
5. Identification and contractual agreements with clinical research vendors to support studies as needed, including but not limited to:
   a. Clinical laboratories
   b. Remote data entry
   c. Investigational product packaging, labeling and shipping
   d. Interactive voice response systems for subject randomization and tracking
6. Data management and Biostatistics including but not limited to:
   a. Case Report Form (CRF) design and database development/implementation
   b. Establishment and maintenance of a centralized data reporting system to track the performance of all clinical support service activities, e.g. clinical specimen tracking system, radiological diagnostic data system
   c. Design and execution of a statistical analysis plan
   d. Real time data-access
   e. Database off-site backup and retention post-trial completion
7. Quality metrics
   a. Implementation of an effective internal Quality Assurance and Quality Control plan for the Offeror's coordinating and documented preparation activities
   b. Development and implementation of a Quality Assurance and Quality Control plan to ensure clinical sites comply with domestic and country-specific regulations governing research with human subjects
   c. An established internal system to measure, monitor and improve the level of performance of the personnel responsible for direct management of the sites (e.g. CRA monitoring activities, CTA essential records management)
8. Clinical site management
   a. Have the in house capability, or through established subcontract relationships to conduct a broad range of activities involved in clinical studies including but not limited to: clinical site(s) selection, clinical and research laboratory support, statistical design and analyses functions, data collection including electronic data entry, data management services, product or specimen labeling, as well as storage and transport of investigational product and clinical specimens
   b. Have current access to a network of sites/investigators available to perform clinical studies; including sites with access to special populations such as the elderly, immuno-compromised, neurologically impaired, children and infants
   c. Plan and conduct pre-study activities related to the clinical site readiness including clinical site training for protocols and development of successful subject recruitment strategies

d. Development and implementation of clinical site quality management programs; including data quality assessments, source data validation, and data master files, and perform quality audits. The Contractor shall also have well designed and regularly instituted clinical site quality checks on study personnel performance as well as study specific regulatory and SOP documents
e. Establishment and maintenance of centralized data reporting systems to track individual site activities such as numbers of subjects screened, enrolled, withdrawn and completed, percentage of CRF reviewed and locked
f. Develop and maintain a system to monitor all clinical site items that require expiratory dates such as site personnel professional licensures, IRB initial approval and periodic IRB status reports, Federal Wide Assurance certification, equipment inspections, temperature monitoring or calibration, and laboratory license(s)
g. Risk management clinical site contingency plans for slow enrollment such as frequent meetings with the clinical sites and identification and pre-qualification of back-up clinical sites

C.3.2. Objective 2: Clinical Trial Response Readiness

Successful Offerors shall provide clinical study execution services, as described in Objective 1, for CBRN, PI and EID MCMs. RTORs will be divided into two components – preparedness and response.

C.3.2.1. Preparedness

Offerors may be required to perform the following activities to prepare for a clinical trial during a public health emergency:

- Provide a plan that is ready to execute for the trial to include but not limited to personnel, documentation, regulatory approvals, material and management plans as appropriate
- Test the plan
- Provide Clinical Protocol (CPs)
- Provide Case Report Forms (CRFs)
- Provide Informed Consent forms (ICFs)
- Develop a clinical and safety database in preparation for Clinical database readiness
- Pre-identify clinical research sites including study budget and contracts in place
- Pre-qualify central laboratories for validated assays
- Provide documented product delivery, storage and pharmaceutical product accountability procedures
- Obtain Institutional Review Board (IRB) approval of the clinical protocols, annotated CRFs and ICFs. (National IRB if available/appropriate)
- Establish an identified project team. The project team may include a clinical research associate, safety monitor, data manager, regulatory specialist, medical writer, project manager and pharmacovigilance specialist.
- Document data flow and sample handling processes (lab manual)

- Gather clinical data
- Annual review and renewal of the plan

Specific roles for BARDA and the Contractor will be established at the time of TO.

C.3.2.2. Response

Offerors shall commit upon Task Order (TO) award to start the study within defined timelines. The protocols for these studies may be established prior to the public health emergency, or created at the time of the public health emergency.

During an event, the Contractor shall provide a dedicated project team to handle the site/patient management, enrollment, data capture and pharmacovigilance responsibilities for the protocols. Once the initial protocols are fully enrolled and the data cleaned and locked, the Contractor will provide draft clinical study reports within the defined timelines. After BARDA review of the draft documents, the Contractor will provide a completed CSR for BARDA's approval and issuance within the defined timeline.

C.4. DELIVERY SCHEDULE

The schedule for delivery of services is set forth below in SECTION F.

C.5. EARNED VALUE MANAGEMENT SYSTEM

C.5.1. Earned Value Management System Plan

Subject to the requirements under HHSAR Clause 352.234-3, the Contractor shall use principles of Earned Value Management System (EVMS) in the management of any work ordered under a cost reimbursement Task Order that exceeds the cost thresholds set forth in HHSAR 334.203(c) and (d). The Seven Principles of EVMS are:

I. Plan all work scope for the program to completion.

II. Break down the program work scope into finite pieces that can be assigned to a responsible person or organization for control of technical, schedule, and cost objectives.

III. Integrate program work scope, schedule, and cost objectives into a performance measurement baseline plan against which accomplishments may be measured. Control Changes to the baseline.

IV. Use actual cost incurred and recorded in accomplishing the work performed.

V. Objectively assess accomplishments at the work performance level.

VI. Analyze significant variances from the plan, forecast impacts, and prepare an estimate at completion based on performance to date and work to be performed.

VII. Use Earned Value information in the company's management processes.

Elements of EVMS shall be applied to all cost reimbursement work under Task Orders that exceed the cost thresholds set forth in HHSAR 334.203(c) and (d) as part of the Integrated Master Project

Plan. The Contractor shall submit a written summary of the management procedures that it will establish, maintain and use to comply with EVMS requirements when proposing on a qualifying Task Order.

C.5.2. Performance Measurement Baseline Review (PMBR)

The Contractor shall submit a plan for a PMBR to occur within 90 days of the award of a Task Order of sufficient size and cost to require EVMS. At the PMBR, the Contractor and the contracting officer shall mutually agree upon the budget, schedule and technical plan baselines (Performance Measurement Baseline). These baselines shall be the basis for monitoring and reporting progress throughout the life of the contract. The PMBR is conducted to achieve confidence that the baselines accurately capture the entire technical scope of work, are consistent with contract schedule requirements, are reasonably and logically planned, and have adequate resources assigned. The goals of the PMBR are as follows:

1. Jointly assess areas such as the Contractor's planning for complete coverage of the SOW, logical scheduling of the work activities, adequate resources, and identification of inherent risks
2. Confirm the integrity of the Performance Measurement Baseline (PMB)
3. Foster the use of EVM as a means of communication
4. Provide confidence in the validity of Contractor reporting
5. Identify risks associated with the PMB
6. Present any revised PMBs for approval
7. Present an Integrated Master Schedule: The Contractor shall deliver an initial program level Integrated Master Schedule (IMS) that rolls up all time-phased WBS elements down to the activity level. This IMS shall include the dependencies that exist between tasks. This IMS will be agreed to and finalized at the PMBR. DI-MGMT-81650 may be referenced as guidance in creation of the IMS (see http://www.acq.osd.mil/pm/).
8. Present the Risk Management Plan. The Contractor shall develop and maintain a risk management plan that highlights potential problems and/or issues that may arise during the life of the contract, their impact on cost, schedule and performance, and appropriate remediation plans. This plan should reference relevant SOW elements where appropriate. The USG has provided a Risk Mitigation Matrix template, Attachment 09, in SECTION J to be completed by any prospective Contractor.

C.5.3. Integrated Master Schedule

The Contractor shall submit an updated Integrated Master Schedule in a format agreed upon by BARDA to the COR and the CO for approval prior to the initiation of any work to be performed under a Task Order of sufficient size and cost to require EVMS. The Integrated Master Schedule shall be incorporated into the contract, and will be used to monitor performance of the contract. The Contractor shall include the key milestones and Go/No Go decision gates. The Contractor will include BARDA Portfolio Management Milestones in their IMS and provide monthly updates. This IMS shall include the following fields at a minimum; baseline start and finish, forecast start and

finish; actual start and finish, predecessor and/or successor. The Contractor shall deliver the Integrated Master Schedule, viewed at the work package level in MS Project file format.

C.6. QUALITY CONTROL/ QUALITY ASSURANCE

The Contractor shall develop a quality control (QC)/quality assurance (QA) monitoring plan that ensures compliance with federal and local regulations, and the ethics committee approved protocol.

C.7. MEETINGS

The Contractor and BARDA shall participate in regular meetings to coordinate and oversee the contracting effort as requested by the Contracting Officer (CO)/Contracting Officer's Representative (COR). Such meetings may include, but are not limited to, site visits to the Contractor's and/or subcontractor's facilities, and meetings with individual Contractors and other HHS officials to discuss the technical, regulatory, and ethical aspects of the program. The Contractor shall provide data, reports, and presentations to groups of outside experts and USG personnel and USG-contracted subject matter experts as required by the CO/COR facilitating review of activities.

C.8. REPORTING REQUIREMENTS

See SECTION F for specific reporting requirements.

Performance of the contract will be monitored by the CO/COR on a regular basis. The Contracting Officer will be responsible for inspection and acceptance of deliverables and services. Monitoring of the contract will be based on periodic reporting by the Contractor. The first "kick-off" site visit will be convened within 30 days of contract award to review HHS procedures, processes and expectations, as well as Contractor's data and plans. Program assessment will be performed by qualified subject matter experts.

C.9. SECURITY PLAN

The Contractor's Security Plan will be included as an attachment to any contract awarded under this solicitation upon approval by the Contracting Officer.

SECTION D – PACKAGING, MARKING AND SHIPPING

D.1. METHOD OF DELIVERY

Unless otherwise specified by the Contracting Officer, delivery of all deliverable items described in to be furnished to the government under this contract (including invoices) shall be made by first class mail, overnight carrier, or email as described in SECTION F.3.

SECTION E – INSPECTION AND ACCEPTANCE

E.1. INSPECTION AND ACCEPTANCE

Inspection and acceptance of the product, services, and documentation called for herein shall be accomplished by the Contracting Officer or a duly authorized representative. Technical inspection and acceptance will be take place at:

Biomedical Advanced Research and Development Authority
Office of the Assistant Secretary for Preparedness and Response
330 Independence Avenue, S.W.
Room G640
Washington, D.C. 20201

E.2. FEDERAL ACQUISITION REGULATION CLAUSES INCORPORATED BY REFERENCE

This contract incorporates the following clause by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available.

FAR 52.246-4, Inspection of Services - Fixed Price (August 1996)

FAR 52.246-5, Inspection of Services - Cost-Reimbursement (April 1984)

FAR 52.246-9, Inspection of Research and Development (Short Form) (April 1984)

FAR 52.246-16, Responsibility for Supplies (April 1984)

SECTION F – DELIVERIES OR PERFORMANCE

F.1. PERIOD OF PERFORMANCE

The period of performance of this contract is anticipated for TWENTY FOUR months from date of award. The period of performance may be extended with the exercise of options, structured as CLINs, as set forth in SECTION B.

F.2. DELIVERIES

Successful performance of the final contract shall be deemed to occur upon performance of the work described in the Statement of Objectives in SECTION C of this contract and upon delivery and acceptance of the items described in SECTION F.3 by the Contracting Officer or their duly authorized representative.

Deliverables will be further defined upon the issuance of specific Task Orders.

F.3. CONTRACT DELIVERABLES AND REPORTING REQUIREMENTS

F.3.1. Submission of Contract Deliverables

Documents should be delivered electronically to the Contracting Officer (CO) and the Contracting Officer's Representative (COR). Unless otherwise specified by the Contracting Officer all deliverables and reports furnished to the Government under the resultant contract (including invoices) shall be addressed as follows:

Contracting Officer HHS/ASPR/AMCG 330 Independence Avenue, S.W., Room G640 Washington, DC 20201 Email: TBD	Contracting Officer Representative HHS/ASPR/BARDA 330 Independence Avenue, S.W., Room G640 Washington, DC 20201 Email: TBD

F.3.2. Reporting Requirements

In addition to those reports required by other terms of this contract, the Contractor(s) shall submit to the CO and the COR technical progress reports as identified in the TO. These reports shall be subject to the technical inspection and requests for clarification by the COR. These reports shall be brief and factual and prepared in accordance with the following format:

F.3.2.1. Safety Reports

Serious Adverse Events (SAEs) that are designated as possibly or probably associated with the administration of the drug/use of the product or Suspected Unexpected Serious Adverse Reaction (SUSARs) shall be reported by e-mail and phone calls to the COR and CO within 24 hours of knowledge of the event. Essential information including the SAE descriptive narrative and initial/follow-up information received from the investigative site including the subject number, the

onset and resolution of the event, the investigator's assessment of severity, if any medical intervention was used to resolve the event or its intensity and if the drug was discontinued should be included in the communication.

Protocol deviations that impact patient safety should be reported within no more than 24 hours from Contractor knowledge of the event.

F.3.2.2 Monthly Technical Progress Reports

During periods in which work is being performed under a TO, Monthly Technical Progress Reports are due on the fifteenth (15th) calendar day of each month for the previous calendar month or within fifteen (15) days past the achievement of project milestones, the Contractor shall submit a report to the COR and the CO. The Contractor shall submit a separate Monthly Technical Progress Report for each TO under which work is being performed. Monthly Technical Progress Reports are not required for periods with no active Task Orders.

The format and type of Monthly Technical Progress Report and Executive Summary will be provided by the COR within fifteen (15) calendar days of contract award. Monthly Technical Progress Reports will include project timelines, milestones and summaries. A Monthly Technical Progress Report will not be required for the period when a Quarterly Technical Report or Final Technical Report is due. The Contractor shall submit one copy of the Monthly Technical Progress Report electronically via e-mail to the COR and the CO.

The report shall be submitted in Microsoft Word, Microsoft Excel, Microsoft PowerPoint, Microsoft Project or compatible, editable formats. Technical Progress reports shall, at a minimum, include the following information:

Title Page: The Technical Progress Report title page shall include the contract number and title, the period of performance or milestone being reported, the contractor's name, address, and other contact information, the author(s), and the date of submission.

Distribution List: A list of persons receiving the Technical Progress report.

Introduction/ Background: An introduction covering the purpose and scope of the report.

Summary: A table organized by Task Order summarizing:

Ongoing activities including but not limited to protocol and CRF development, clinical site assessments, regulatory document preparation, enrollment, safety issues, interim analysis, CSR construction

If there are ongoing clinical studies, the study's number and percent of target enrollment, overall clinical site performance status, and clinical site training status.

If work is being performed under a TO with EVM requirements, Budgeted Cost of Work Performed, Budgeted Cost of Work Scheduled, Actual Cost of Work

Performed, Schedule Performance Index and Cost Performance Index should also be reported.

Progress: The report shall detail, document and summarize, organized by Task Order, the results of work performed, test results and milestones achieved during the period covered. Progress should be represented as % of total project plan completed, as well as % completed for the month based on forecasted for the month. Information supporting the summary shall also be provided.

A summary of work and travel planned for the next reporting period shall be included. During active clinical studies an update on subject recruitment in terms of numbers screened, numbers enrolled and drop-outs will be provided per clinical site.

Issues: Issues resolved, new issues and outstanding issues shall be enumerated with options and recommendations for resolution. An explanation of any difference between planned progress and actual progress, why the differences have occurred, and, if project activity is delinquent, then what corrective steps are planned. Revised timelines shall be provided.

Invoices: Summary of any invoices submitted during the reporting period.

Action Items: Summary table of activities or tasks to be accomplished by a certain date and by whom.

Attachments: Each report will include an attachment with an up to date contract history including invoice submission/acceptance dates, and modifications. Results on the project are provided as attachments where appropriate.

F.3.2.3. Quarterly Technical Progress Reports

The format and type of the Quarterly Technical Progress Report and Executive Summary will be provided by the COR within fifteen (15) calendar days of contract award. Quarterly Technical Progress Reports will include project summaries as well as performance metrics for the prime contractor. A Quarterly Technical Progress Report will not be required for the period when the Final Technical Report is due. The Contractor shall submit one copy of the Quarterly Technical Progress Report electronically via e-mail to the COR and the CO. The report shall be submitted in Microsoft Word, Microsoft Excel, Microsoft PowerPoint, Microsoft Project or compatible, editable formats. Quarterly Technical Progress Reports are required for periods with no active Task Orders. Quarterly Technical Progress reports shall, at a minimum, include the following information:

Title Page: The Quarterly Technical Progress Report title page shall include the contract number and title, the period of performance being reported, the contractor's name, address, and other contact information, the author(s), and the date of submission.

Distribution List: A list of persons receiving the Technical Progress report.

Introduction/ Background: An introduction covering the purpose and scope of the report.

Summary: A table organized by Task Order summarizing ongoing activities.

Progress: The report shall summarize, organized by Task Order, the results of work performed. Progress should be represented as % of total project plan completed, as well as % completed for the quarter based on forecasted for the quarter. Information supporting the summary shall also be provided. A summary of work and travel planned for the next reporting period shall also be provided.

Issues: Issues resolved, new issues and outstanding issues shall be enumerated with options and recommendations for resolution. An explanation of any difference between planned progress and actual progress, why the differences have occurred, and, if project activity is delinquent, then what corrective steps are planned. Revised timelines shall be provided.

Quality Metrics: For active clinical studies (not exclusively those funded by BARDA):

- Update subject recruitment (numbers screened, numbers enrolled and drop-outs per clinical site).
- Contractor staff stability (over each quarter) for CRAs, Project Manager, Regulatory and other personnel.
- Clinical study Trip Report timeliness.
- Queries as a measure of whether the clinical study PMs and CRAs are in control of their studies.

Invoices: Summary of any invoices submitted during the reporting period.

Action Items: Summary table of activities or tasks to be accomplished by a certain date and by whom.

Attachments: Each report will include an attachment with an up to date contract history including invoice submission/acceptance dates, and modifications. Results on the project are provided as attachments where appropriate.

F.3.2.4. Executive Summary

The Executive Summary shall accompany each Technical Progress Report, be formatted as a Microsoft PowerPoint presentation, and include the following:

Title page: Executive Title, the contract number and title, the period of performance or milestone being reported, the contractor's name and the date of submission.

Project Progress: Presented as milestone events, test results, tasks and other activities achieved during the reporting period as talking point bullets.

Project Issues: Presented headings and each item as a talking point bullet.

F.3.2.5. Final Technical Report

For each TO, a Final Technical closeout report will be compiled. The Final Technical Closeout Report will include the following:

Title page: containing Executive Title, the contract number and title, TO Title and period of performance reported, the contractor's name and the date of submission.

Project Progress: presented as milestone target and accomplishment, test results, tasks and other activities achieved during the reporting period as talking point bullets.

Project Issues and Resolutions: presented headings and each item as a talking point bullet.

Summary Project Results: Summary of the final Clinical Study Report, Adverse Events, primary and other endpoints.

F.3.2.6. Final Closeout Report

The Contractor shall submit a comprehensive Final Report that details, documents, and summarizes the results of the entire contract work. The report shall explain comprehensively the results achieved. It shall also contain a summary of all Task Orders issued under the contract and a determination that everything under the contract has been completed and accepted. A draft Final Report shall be submitted to the CO and COR for review and comment at least 45 days prior to contract expiration date. Upon final acceptance by the CO, an electronic copy shall be submitted to the CO not later than 30 days following the expiration date of the contract.

F.3.2.7. Deliverable Schedule

Below is a summary of deliverables, reporting procedures and the deliverable schedule:

Item	Description	Quantity	Addresses	Deliverable Schedule
Reports				
1)	Safety Report	2 electronic	CO: (1) electronic copy COR: (1) electronic copy	Within 24 hours of knowledge of the event. Protocol deviations that impact patient safety should be reported within no more than 24 hours from Contractor knowledge of the event.
2)	Monthly Technical Progress Report	2 electronic	CO: (1) electronic copy COR: (1) electronic copy	The 15th calendar day of each month following the first full month of the contract award. The Monthly Technical Progress Report will not be required on months when a Quarterly Technical Progress Report is due.

3)	Quarterly Technical Progress Report	2 electronic	CO: (1) electronic copy COR: (1) electronic copy	The 15th calendar day of the month following the end of each 3 month performance period. The Monthly Technical Progress Report will not be required on months when a Quarterly Technical Progress Report is due.
4)	Executive Summary	2 electronic	CO: (1) electronic copy COR: (1) electronic copy	The Executive Summary shall accompany each Technical Progress Report.
5)	Final Technical Report	2 electronic	CO: (1) electronic copy COR: (1) electronic copy	30 days after the end of the period of performance of each Task Order.
6)	Draft Final Closeout Report	2 electronic	CO: (1) electronic copy COR: (1) electronic copy	At least 45 days prior to the expiration date of the contract.
7)	Final Closeout Report	2 electronic	CO: (1) electronic copy COR: (1) electronic copy	30 days after the expiration date of the contract.

F.4. FEDERAL ACQUISITION REGULATION CLAUSES INCORPORATED BY REFERENCE

This contract incorporates the following clause(s) by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available. The full text of each clause may be accessed electronically at this address: http://www.acquisition.gov/comp/far/index.html.

FAR 52.242-15, Stop Work Order (August 1989)
FAR 52.242-15, Stop Work Order (August 1989), Alternate 1 (April 1984)

SECTION G – CONTRACT ADMINISTRATION

G.1. CONTRACTING OFFICER (CO)

1) The Contracting Officer (CO) is the only individual who can legally commit the Government to the expenditure of public funds. No person other than the Contracting Officer can make any changes to the terms, conditions, general provisions or other stipulations of this contract.

2) The CO is the only person with authority to act as agent of the Government under this contract. Only the Contracting Officer has authority to: (1) direct or negotiate any changes in the statement of work; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimbursement to the Contractor for any costs incurred during the performance of this contract; (5) obligate or de-obligate funds into the contract; or (6) otherwise change any terms and conditions of this contract.

3) No information, other than that which may be contained in an authorized modification to this contract duly issued by the Contracting Officer, which may be received from any person employed by the United States Government, or otherwise, shall be considered grounds for deviation from any stipulation of this contract.

G.2. CONTRACTING OFFICER'S REPRESENTATIVE (COR)

The Government's Contracting Officer's Representative (COR) is:

To be identified at the time of award of contract

As delegated by the CO, the COR is responsible for: (1) monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the Contracting Officer changes in requirements; (2) assisting the CO in interpreting the statement of work and any other technical performance requirements; (3) performing technical evaluation as required; (4) performing technical inspections required by this contract; and (5) assisting in the resolution of technical problems encountered during performance.

G.3. CONTRACTOR'S POINTS OF CONTACT

The Contractor shall provide primary and secondary points of contact that will be available 24 hours per day, 7 days per week, to be notified in case of a public health emergency.

G.4. ORDERING PROCEDURES

G.4.1. Ordering Official

The **Contracting Officer** is the designated Ordering Official for the contract. The Contracting Officer will sign all orders (including written confirmation of oral/telephonic orders) involving requests for supplies and/or services under this contract. Each delivery shall be accompanied by a packing slip or other evidence of delivery/performance.

G.4.2. Multiple Award Ordering

Fair opportunity will be provided to all prime contractors for each Task Order unless one of the circumstances described in FAR 16.505(b)(2)(i) applies to the order or a statute expressly authorizes or requires that the purchase be made from a specified source. Task Order competitions will utilize best value with "trade-off" analyses. The Government reserves the right to make multiple awards.

G.4.3. Method of Ordering

Each RTOR issued by HHS will include a Statement of Work, Evaluation Factors for Award, Reporting Requirements and Deliverables, required components of the offer to be submitted, format for submission, and any other issues pertinent to the Task Order, including information on whether it is anticipated that the Task Order will be awarded with or without discussions.

Contractors shall be required to respond to all RTORs. Those contractors that are not capable of performing the services described in the RTOR must notify the Contracting Officer in writing on or before the closing date and time established for the RTOR.

In providing services under this contract, the following procedures shall apply to the award of Task Orders. All work required under this contract shall be authorized through execution of an agreement, "Task Order," signed by the Contractor and Contracting Officer. The Task Order may be awarded at any time within the period of performance.

When the Government elects to fill a requirement under this contract, the Contracting Officer shall provide a RTOR to the contractors that receive contracts for the particular part for which responses are being solicited. A RTOR shall, at a minimum include a Statement of Work, evaluation factors, specific reporting requirements, deliverables and delivery schedule, the relevant importance of technical and cost factors, and any special instructions.

The Government may, at its discretion, award Task Orders with optional work packages or periods of performance. The Contractor performing the Task Order may be required to perform the optional work packages or periods of performance at the sole discretion of the Government. For example, completion of the work specified in the Task Order base period may require the development of a plan to respond to a Public Health Medical Emergency. Completion of the work in the Task Order option period may require the execution, during a Public Health Medical Emergency, of the plan developed in the base period.

If necessary, the Contracting Officer will arrange a meeting between contractors and the Contracting Officer to discuss the proposed Task Order prior to submitting Task Order proposals (technical and business). Business proposals shall include appropriate support of all costs proposed as necessary for performing the services identified in the Task Order.

Within the time allowed for proposals preparation (time allowed for proposal preparation and submission will vary depending on the task and will be designated in each Task Order), contractors shall submit their proposals in response to a Task Order, which shall include, but not necessarily limited to the following information:

1. Statement that the Contractor has a clear understanding of the task requirement.
2. Statement of technical and managerial resources and expertise the Contractor can provide to satisfy the requirement;

3. A schedule of performance, identify major milestones, deliverables and delivery date, and task completion; and
4. A cost schedule necessary to complete the work.

The Government will evaluate proposals and conduct negotiations as necessary. Task Orders will be awarded to the contractor whose proposals is determined to be the most advantageous to the Government based on the technical and cost factors specified in the RTOR. The Government reserves the right to make an award on the most favorable initials proposal without discussions.

The contracting officer is the only individual authorized to issue a Task Order under this contract. Unless specifically authorized by the contracting officer, the Contractor shall not commence work on a requirement until a fully executed Task Order has been awarded.

G.4.4. Minimum and Maximum Quantity

Minimum and maximum ordering quantities are discussed in SECTION B.5.

G.4.5. Option to Extend the Term of the Contract

The Government may exercise options, in accordance with FAR 17.207, to extend the term of the contract beyond the base period. The exercise of options increases minimum quantity specified in SECTION B.5.

G.5. PAYMENT BY ELECTRONIC FUNDS TRANSFER (Oct 2003)

The Government shall use electronic funds transfer to the maximum extent possible when making payments under this contract. FAR 52.232-33, Payment by Electronic Funds Transfer–Central Contractor Registration, in Section I, requires the Contractor to designate in writing a financial institution for receipt of electronic funds transfer payments.

G.6. INVOICE SUBMISSION

(a) The Contractor shall submit invoices to the Contracting Officer at the address provided in SECTION F.3. Unless otherwise specified by the Contracting Officer, two hard copies of the invoice shall be delivered by first class mail to the CO with a courtesy copy to be sent by electronic mail. The invoice shall be deemed as 'received' upon receipt of the hard copy of the invoice at the address provided. A sample invoice form is provided in SECTION J – Attachment 7.

(b) The Contractor agrees to include (as a minimum) the following information on each invoice:
   (1) Contractor's Name & Address
   (2) Contractor's Tax Identification Number (TIN)
   (3) Contract Number
   (4) Invoice Number
   (5) Invoice Date
   (6) Contract Line Item Number
   (7) Quantity
   (8) Unit Price & Extended Amount for each line item
   (9) Total Amount of Invoice
   (10) Name, title and telephone number of person to be notified in the event of a defective invoice

(11)Payment Address, if different from the information in (b) (1).

(c) The Contractor shall not submit an invoice prior to delivery of goods or services. .

G.7. CONTRACT COMMUNICATIONS/CORRESPONDENCE

The Contractor shall identify all correspondence, reports, and other data pertinent to this contract by imprinting thereon the contract number from Page 1 of the contract.

G.8. EVALUATION OF CONTRACTOR PERFORMANCE

(a) *Purpose:* In accordance with FAR 42.1502, the contractor's performance will be periodically evaluated by the government in order to provide current information for source selection purposes. These evaluations will therefore be marked "Source Selection Information."

(b) *Performance Evaluation Period*: The contractor's performance will be evaluated at least annually.

(c) *Evaluators*: The performance evaluation will be completed jointly by the Contracting Officer's Representative and the Contracting Officer.

(d) *Performance Evaluation Factors*: The contractor's performance will be evaluated in accordance with Section J, Attachment 10, Contract Performance Evaluation Report.

(e) *Contractor Review*: A copy of the evaluation will be provided to the contractor as soon as practicable after completion of the evaluation. The contractor shall submit comments, rebutting statements, or additional information to the Contracting Officer within 30 calendar days after receipt of the evaluation.

(f) *Resolving Disagreements between the Government and the Contractor*: Disagreements between the parties regarding the evaluation will be reviewed at a level above the Contracting Officer. The ultimate conclusion on the performance evaluation is a decision of the contracting agency. Copies of the evaluation, contractor's response, and review comments, if any, will be retained as part of the evaluation.

(g) *Release of Contractor Performance Evaluation Information*: The completed evaluation will not be released to other than Government personnel and the contractor whose performance is being evaluated. Disclosure of such information could cause harm both to the commercial interest of the Government and to the competitive position of the contractor being evaluated, as well as impede the efficiency of Government operations.

(h) *Source Selection Information*: Departments and agencies may share past performance information with other Government departments and agencies when requested to support future award decisions. The information may be provided through interview and/or by sending the evaluation and comment document to the requesting source selection official.

(i) *Retention Period*: The agency will retain past performance information for a maximum period of 3 years after completion of contract performance for the purpose of providing source selection information for future contract awards.

G.9. KEY PERSONNEL

The personnel specified in this contract are considered to be essential to the work being performed hereunder. Prior to diverting any of the specified individuals to other programs, the Contractor shall notify the Contracting Officer reasonably in advance and shall submit justification (including proposed substitutions) in sufficient detail to permit evaluation of the impact on the program. No diversion shall be made by the Contractor without the written consent of the Contracting Officer; provided that the Contracting Officer may ratify in writing that such diversion and such ratification shall constitute the consent of the Contracting Officer required by this clause. The contract may be modified from time to time during the course of the contract to either add or delete personnel as appropriate.

Key Personnel: To be identified at the time of award of contract.

SECTION H – SPECIAL CONTRACT REQUIREMENTS

H.1. PROTECTION OF HUMAN SUBJECTS, HHSAR 352.270-4(b) (January 2006)

a. The Contractor agrees that the rights and welfare of human subjects involved in research under this contract shall be protected in accordance with 45 CFR Part 46 and with the Contractor's current Assurance of Compliance on file with the Office for Human Research Protections (OHRP), Department of Health and Human Services. The Contractor further agrees to provide certification at least annually that the Institutional Review Board has reviewed and approved the procedures, which involve human subjects in accordance with 45 CFR Part 46 and the Assurance of Compliance.

b. The Contractor shall bear full responsibility for the performance of all work and services involving the use of human subjects under this contract and shall ensure that work is conducted in a proper manner and as safely as is feasible. The parties hereto agree that the Contractor retains the right to control and direct the performance of all work under this contract. The Contractor shall not deem anything in this contract to constitute the Contractor or any subcontractor, agent or employee of the Contractor, or any other person, organization, institution, or group of any kind whatsoever, as the agent or employee of the Government. The Contractor agrees that it has entered into this contract and will discharge its obligations, duties, and undertakings and the work pursuant thereto, whether requiring professional judgment or otherwise, as an independent contractor without imputing liability on the part of the Government for the acts of the Contractor or its employees.

c. If at any time during the performance of this contract, the Contracting Officer determines, in consultation with OHRP that the Contractor is not in compliance with any of the requirements and/or standards stated in paragraphs (a) and (b) above, the Contracting Officer may immediately suspend, in whole or in part, work and further payments under this contract until the Contractor corrects the noncompliance. The Contracting Officer may communicate the notice of suspension by telephone with confirmation in writing. If the Contractor fails to complete corrective action within the period of time designated in the Contracting Officer's written notice of suspension, the Contracting Officer may, after consultation with OHRP, terminate this contract in whole or in part, and the Contractor's name may be removed from the list of those contractors with approved Human Subject Assurances.

H.2. CLINICAL RESEARCH

These Clinical Terms apply to all grants and contracts that involve clinical research.

The Government shall have unlimited rights to all protocols, data generated from the execution of these protocols, and final reports, funded by the Government under this contract, as defined in Rights in Data Clause in FAR 52.227-14. The Government reserves the right to request that the Contractor provide any contract deliverable in a non-proprietary form, to ensure the Government has the ability to review and distribute the deliverables, as the Government deems necessary.

H.2.1 Safety and Monitoring Issues

Institutional Review Board (IRB) or Independent Ethics Committee (IEC) Approval

Before award and then with the annual progress report, the Contractor must submit to the Government a copy of the current IRB or IEC approved informed consent document, documentation of continuing review and approval and the Office of Human Research Protections (OHRP) FWA number for the institution or site.

If other institutions are involved in the research (e.g., a multicenter clinical trial or study), each institution's IRB or IEC must review and approve the protocol. They must also provide the Government initial and annual documentation of continuing review and approval, including the current approved informed consent document and FWA number.

The grantee institution must ensure that the applications as well as all protocols are reviewed by their IRB or IEC.

To help ensure the safety of participants enrolled in BARDA-funded studies, the Contractor must provide the Government a summary explanation and copies of documents related to all major changes in the status of ongoing protocols, including the following:

1. All amendments or changes to the protocol, identified by protocol version number, date, or both and date it is valid.
2. All changes in informed consent documents, identified by version number, date, or both and dates it is valid.
3. Termination or temporary suspension of patient accrual.
4. Termination or temporary suspension of the protocol.
5. Any change in IRB approval.
6. Any other problems or issues that could affect the participants in the studies.

Contractors must notify BARDA through the Contracting Officer's Technical Representative (COR) or Contracting Officer (CO) of any of the above changes within 24 hours by email, followed by a letter signed by the institutional business official, detailing notification of the change of status to the local IRB and a copy of any responses from the IRB or IEC.

If a clinical protocol has been reviewed by an Institutional Bio-safety Committee (IBC) or the NIH Recombinant DNA Advisory Committee (RAC), the Contractor must provide information about the initial and ongoing review and approval, if any. See the NIH Guidelines for Research Involving Recombinant DNA Molecules.

H.2.2. Data and Safety Monitoring Requirements

The Contractor may be required to conduct independent safety monitoring for clinical trials of investigational drugs, devices, or biologics; clinical trials of licensed products; and clinical research of any type involving more than minimal risk to volunteers. Independent monitoring can take a variety of forms. Phase III clinical trials must have an assigned independent data and safety monitoring board (DSMB); other trials may require DSMB oversight as well. The Contractor shall inform the Government of any upcoming site visits and/or audits of Contractor facilities funded under this effort. BARDA reserves the right to accompany the Contractor on site visits and/or audits of Contractors and Subcontractors as the Government deems necessary.

The type of monitoring to be used shall be mutually agreed upon between the Contractor and the Government before enrollment starts. Discussions with the responsible BARDA COR regarding appropriate safety monitoring and approval of the final monitoring plan by BARDA must occur before patient enrollment begins and may include discussions about the appointment of one of the following:

1. **Independent Safety Monitor** – a physician or other appropriate expert who is independent of the study and available in real time to review and recommend appropriate action regarding adverse events and other safety issues.
2. **Independent Monitoring Committee (IMC) or Safety Monitoring Committee (SMC)** – a small group of independent investigators and biostatisticians who review data from a particular study.
3. **Data and Safety Monitoring Board** – an independent committee charged with reviewing safety and trial progress and providing advice with respect to study continuation, modification, and termination. The Contractor may be required to use an established BARDA DSMB or to organize an independent DSMB. All phase III clinical trials must be reviewed by a DSMB; other trials may require DSMB oversight as well. Please refer to: NIAID Principles for Use of a Data and Safety Monitoring Board (DSMB) For Oversight of Clinical Trials Policy. The Government retains the right to place a nonvoting member on the DSMB.

When a monitor or monitoring board is organized, a description of it, its charter or operating procedures (including a proposed meeting schedule and plan for review of adverse events), and roster and *curriculum vitae* from all members must be submitted to and approved by the Government before enrollment starts.

Additionally, the Contractor must submit written summaries of all reviews conducted by the monitoring group to the Government within 30 days of reviews or meetings.

H.2.3. BARDA Protocol Review Process Before Patient Enrollment Begins

BARDA has a responsibility to ensure that mechanisms and procedures are in place to protect the safety of participants in BARDA-supported clinical trials. Therefore, before patient accrual or participant enrollment, the Contractor must provide the following (as applicable) for review and approval by the Government:

1. IRB or IEC approved clinical research protocol identified by version number, date, or both, including details of study design, proposed interventions, patient eligibility, and exclusion criteria.
2. Documentation of IRB or IEC approval, including OHRP FWA number, IRB or IEC registration number, and IRB or IEC name.
3. IRB or IEC approved informed consent document, identified by version number, date, or both and date it is valid.
4. Plans for the management of side effects.
5. Procedures for assessing and reporting adverse events.
6. Plans for data and safety monitoring (see B above) and monitoring of the clinical study site, pharmacy, and laboratory.

7. Documentation that the Contractor and all study staff responsible for the design or conduct of the research have received Good Clinical Practice (GCP) training in the protection of human subjects.

BARDA comments will be forwarded to the Contractor within two weeks (10 business days) of receipt of the above information. The Contractor must address in writing all study design, safety, regulatory, ethical, and conflict of interest concerns raised by the BARDA COR to the satisfaction of the Government before patient accrual or participant enrollment can begin. After the Government receives the corrected documentation, a written Contract Officer Authorization (COA) Letter will be provided to the Contractor. This COA provides authorization to the Contractor to execute the specific clinical study funded in part or in whole by the Government.

H.2.4. Required Time-Sensitive Notification

Under an IND or IDE, the sponsor must provide FDA safety reports of serious adverse events. Under these Clinical Terms of Award, the Contractor must submit copies to the responsible BARDA Contracting Officer's representative (COR) as follows:

1. *Expedited safety report of unexpected or life-threatening experience or death* – A copy of any report of unexpected or life-threatening experience or death associated with the use of an IND drug, which must be reported to FDA by telephone or fax as soon as possible but no later than seven days after the IND sponsor's receipt of the information, must be submitted to the BARDA program officer or the contracting officer's technical representative within 24 hours of FDA notification.
2. *Expedited safety reports of serious and unexpected adverse experiences* – A copy of any report of unexpected and serious adverse experience associated with use of an IND drug or any finding from tests in laboratory animals that suggests a significant risk for human subjects, which must be reported in writing to FDA as soon as possible but no later than 15 days after the IND sponsor's receipt of the information, must be submitted to the BARDA Contracting Officer's Representative within 24 hours of FDA notification.
3. *IDE reports of unanticipated adverse device effect* – A copy of any reports of unanticipated adverse device effect submitted to FDA must be submitted to the BARDA Contracting Officer's Representative within 24 hours of FDA notification.
4. *Expedited safety reports* – should be sent to the BARDA COR concurrently with the report to FDA.
5. Other adverse events documented during the course of the trial should be included in the annual IND or IDE report and reported to the BARDA annually.

In case of problems or issues, the BARDA COR will contact the Contractor within 10 working days by email, followed within 7 calendar days by an official letter to the Contractor. The Contractor shall forward the official letter to the principal investigator listing issues and appropriate actions to be discussed.

Safety reporting for research not performed under an IND or IDE

Ongoing safety reporting requirements for research not performed under an IND or IDE shall be mutually agreed upon by the BARDA Contracting Officer's Representative and the Contractor.

H.3. HUMAN MATERIALS (ASSURANCE OF OHRP COMPLIANCE)

The acquisition and supply of all human specimen material (including fetal material) used under this contract shall be obtained by the Contractor in full compliance with applicable State and Local laws and the provisions of the Uniform Anatomical Gift Act in the United States, and no undue inducements, monetary or otherwise, will be offered to any person to influence their donation of human material.

The Contractor shall provide written documentation that all human materials obtained as a result of research involving human subjects conducted under this contract, by collaborating sites, or by subcontractors identified under this contract, were obtained with prior approval by the Office for Human Research Protections (OHRP) of an Assurance to comply with the requirements of 45 CFR 46 to protect human research subjects. This restriction applies to all collaborating sites without OHRP-approved Assurances, whether domestic or foreign, and compliance must be ensured by the Contractor.

Provision by the Contractor to the Contracting Officer of a properly completed "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263(formerly Optional Form 310), certifying IRB review and approval of the protocol from which the human materials were obtained constitutes the written documentation required. The human subject certification can be met by submission of a self designated form, provided that it contains the information required by the "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263(formerly Optional Form 310).

H.4. NEEDLE DISTRIBUTION

The Contractor shall not use contract funds to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.

H.5. ACKNOWLEDGEMENT OF FEDERAL FUNDING

The Contractor shall clearly state, when issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money: (1) the percentage of the total costs of the program or project which will be financed with Federal money; (2) the dollar amount of Federal funds for the project or program; and (3) the percentage and dollar amount of the total costs of the project or program that will be financed by nongovernmental sources.

H.6. RESTRICTION ON ABORTIONS

The Contractor shall not use contract funds for any abortion.

H.7. CONTINUED BAN ON FUNDING OF HUMAN EMBRYO RESEARCH

The Contractor shall not use contract funds for (1) the creation of a human embryo or embryos for research purposes; or (2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.204(b) and Section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)). The term "human embryo or embryos" includes any organism, not protected as a human subject under 45 CFR 46 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells.

Additionally, in accordance with a March 4, 1997 Presidential Memorandum, Federal funds may not be used for cloning of human beings.

H.8. DISSEMINATION OF FALSE OR DELIBERATELY MISLEADING INFORMATION

The Contractor shall not use contract funds to disseminate information that is deliberately false or misleading.

H.9. OPTION PROVISION

Unless the Government exercises its option pursuant to the Option Clause set forth in ARTICLE I.3., the contract will consist only of the Base Period of the Statement of Work as defined in Sections C and F of the contract. Pursuant to FAR 52.217-9, Option to Extend the Term of the Contract, set forth in ARTICLE I of this contract, the Government may, by unilateral contract modification, require the Contractor to perform additional options set forth in the Statement of Work and also defined in Sections C and F of the contract. If the Government exercises this option, notice must be given at least 60 days prior to the expiration date of this contract, and the minimum ordering amount of the contract will be increased as set forth in the OPTION PRICES Article in SECTION B of this contract.

In accordance with FAR 16.505(b)(5), the following individual has been designated as the HHS/ASPR Ombudsman for task order and delivery order contracts:

[The appropriate individual will be identified in any resultant contract]

H.10. SUBCONTRACTING PROVISIONS

a. **Small Business Subcontracting Plan**

1. The Small Business Subcontracting Plan, dated _____ is attached hereto and made a part of this contract.
2. The failure of any Contractor or subcontractor to comply in good faith with FAR Clause 52.219-8, entitled "Utilization of Small Business Concerns" incorporated in this contract and the attached Subcontracting Plan, will be a material breach of such contract or subcontract and subject to the remedies reserved to the Government under FAR Clause 52.219-16 entitled, "Liquidated Damages-Subcontracting Plan."

b. **Subcontracting Reports**

The Contractor shall submit the following Subcontracting reports electronically via the "electronic Subcontracting Reporting System (eSRS) at http://www.esrs.gov .

1. Individual Subcontract Reports (ISR)
   Regardless of the effective date of this contract, the Report shall be due on the following dates for the entire life of this contract:

   April 30th
   October 30th

Expiration Date of Contract

2. Summary Subcontract Report (SSR)
   Regardless of the effective date of this contract, the Summary Subcontract Report shall be submitted annually on the following date for the entire life of this contract:

   October 30th

For both the Individual and Summary Subcontract Reports, the Contracting Officer shall be included as a contact for notification purposes at the following e-mail address defined in SECTION F.3.

H.11. CONFIDENTIALITY OF INFORMATION

a. Confidential information, as used in this article, means information or data of a personal nature about an individual, or proprietary information or data submitted by or pertaining to an institution or organization.

b. The Contracting Officer and the Contractor may, by mutual consent, identify elsewhere in this contract specific information and/or categories of information which the Government will furnish to the Contractor or that the Contractor is expected to generate which is confidential. Similarly, the Contracting Officer and the Contractor may, by mutual consent, identify such confidential information from time to time during the performance of the contract. Failure to agree will be settled pursuant to the "Disputes" clause.

c. If it is established elsewhere in this contract that information to be utilized under this contract, or a portion thereof, is subject to the Privacy Act, the Contractor will follow the rules and procedures of disclosure set forth in the Privacy Act of 1974, 5 U.S.C. 552a, and implementing regulations and policies, with respect to systems of records determined to be subject to the Privacy Act.

d. Confidential information, as defined in paragraph (a) of this article, shall not be disclosed without the prior written consent of the individual, institution, or organization.

e. Whenever the Contractor is uncertain with regard to the proper handling of material under the contract, or if the material in question is subject to the Privacy Act or is confidential information subject to the provisions of this article, the Contractor should obtain a written determination from the Contracting Officer prior to any release, disclosure, dissemination, or publication.

f. Contracting Officer determinations will reflect the result of internal coordination with appropriate program and legal officials.

g. The provisions of paragraph (d) of this article shall not apply to conflicting or overlapping provisions in other Federal, State or local laws.

The following information is covered by this article:

[Covered information may be identified in a contract awarded under this solicitation.]

H.12. INSTITUTIONAL RESPONSIBILITY REGARDING INVESTIGATOR FINANCIAL CONFLICTS OF INTEREST

The Institution (includes any contractor, public or private, excluding a Federal agency) shall comply with the requirements of 45 CFR Part 94, Responsible Prospective Contractors, which promotes objectivity in research by establishing standards to ensure that Investigators (defined as the project director or principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded under BARDA contracts, or proposed for such funding, which may include, for example, collaborators or consultants) will not be biased by any Investigator financial conflicts of interest.

If the failure of an Institution to comply with an Institution's financial conflicts of interest policy or a financial conflict of interest management plan appears to have biased the design, conduct, or reporting of the BARDA-funded research, the Institution must promptly notify the Contracting Officer of the corrective action taken or to be taken. The Contracting Officer will consider the situation and, as necessary, take appropriate action or refer the matter to the Institution for further action, which may include directions to the Institution on how to maintain appropriate objectivity in the BARDA-funded research project.

The Contracting Officer and/or HHS may inquire at any time before, during, or after award into any Investigator disclosure of financial interests, and the Institution's review of, and response to, such disclosure, regardless of whether the disclosure resulted in the Institution's determination of a financial conflict of interests. The Contracting Officer may require submission of the records or review them on site. On the basis of this review of records or other information that may be available, the Contracting Officer may decide that a particular financial conflict of interest will bias the objectivity of the BARDA-funded research to such an extent that further corrective action is needed or that the Institution has not managed the financial conflict of interest in accordance with Part 94.6(b). The issuance of a Stop Work Order by the Contracting Officer may be necessary until the matter is resolved.

If the Contracting Officer determines that BARDA-funded clinical research, whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment, has been designed, conducted, or reported by an Investigator with a financial conflict of interest that was managed or reported by the Institution, the shall require the Investigator involved to disclose the financial conflict of interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

H.13. PUBLICATION AND PUBLICITY

The Contractor shall acknowledge the support of the Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority whenever publicizing the work under this contract in any media by including an acknowledgment substantially as follows:

"This project has been funded in whole or in part with Federal funds from the Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority, under Contract No._____"

Press Releases:

The Contractor shall clearly state, when issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money that: (1) the percentage of the total costs of the program or project which will be financed with Federal money; (2) the dollar amount of Federal funds for the project or program; and (3) the percentage and dollar amount of the total costs of the project or program that will be financed by non-Governmental sources.

H.14. REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in BARDA funded programs is encouraged to report such matters to the HHS Inspector General's Office in writing or on the Inspector General's Hotline. The toll free number is **1-800-HHS-TIPS (1-800-447-8477).** All telephone calls will be handled confidentially. The e-mail address is Htips@os.dhhs.gov and the mailing address is:

Office of Inspector General
Department of Health and Human Services
TIPS HOTLINE
P.O. Box 23489
Washington, D.C. 20026

H.15. POSSESSION USE AND TRANSFER OF SELECT BIOLOGICAL AGENTS OR TOXINS

The work being conducted under this contract may involve the possession, use, or transfer of a select agent or toxin. The contractor shall not conduct work involving a Select Agent or Toxin under this contract until it and any associated subcontractor(s) comply with the following:

For prime or subcontract awards to ***domestic institutions*** that possess, use, and/or transfer a Select Agent or Toxin under this contract, the institution must comply with the provisions of 42 CFR part 73, 7 CFR part 331, and/or 9 CFR part 121 (http://www.selectagents.gov/Regulations.html) as required, before using Government funds for work involving a *Select Agent or Toxin*. **No U.S. Government funds can be used for research involving a *Select Agent or Toxin*** at **a domestic institution without a valid registration certificate.**

For prime or subcontract awards to ***foreign institutions*** that possess, use, and/or transfer a *Select Agent or Toxin* , before using BARDA funds for any work directly involving a *Select Agent or Toxin* , the foreign institution must provide information satisfactory to BARDA that safety, security, and training standards equivalent to those described in 42 CFR part 73, 7 CFR part 331, and/or 9 CFR part 121 are in place and will be administered on behalf of all *Select Agent or Toxin* work supported by these funds. The process for making this determination includes a site visit to the foreign site by a BARDA representative. During this visit, the foreign institution must provide the

following information: concise summaries of safety, security, and training plans; names of individuals at the foreign institution who will have access to the Select Agent or Toxin and procedures for ensuring that only approved and appropriate individuals, in accordance with institution procedures, will have access to the Select Agents or Toxins under the contract; and copies of or links to any applicable laws, regulations, policies, and procedures applicable to that institution for the safe and secure possession, use, and/or transfer of select agents. Visits to foreign sites are conducted every three years after the initial review. **No U.S. Government funds can be used for work involving a *Select Agent or Toxin* at a foreign institution without written approval from the Contracting Officer.**

Prior to conducting a restricted experiment with a Select Agent or Toxin under this contract or any associated subcontract, the contractor must discuss the experiment with the Contracting Officer's Representative (COR) and request and obtain written approval from the Contracting Officer. **Domestic institutions** must submit to the Contracting Officer written approval from the CDC to perform the proposed restricted experiment.

For prime or subcontract awards to **foreign institutions** that possess, use, and/or transfer Select Agents under this contract, the foreign institution must include details about the select agent in their technical proposal, including the quantity proposed to be used during contract performance. The foreign institution must also, when requested during negotiations, provide information satisfactory to BARDA that include safety, security, and training standards equivalent to those described in 42 CFR part 73, 7 CFR part 331, and/or 9 CFR part 121 at: http://www.aphis.usda.gov/programs/ag_selectagent/FinalRule3-18-05.pdf for U.S. institutions are in place and will be administered on behalf of all Select Agent work under the resulting contract.

No BARDA funds can be used for a restricted experiment with a Select Agent or Toxin at either a domestic or foreign institution without written approval from the Contracting Officer.

Listings of HHS and USDA select agents and toxins, and overlap select agents or toxins as well as information about the registration process for domestic institutions, are available on the Select Agent Program Web site at http://www.selectagents.gov/ and http://www.selectagents.gov/Select%20Agents%20and%20Toxins%20List.html .

H.16. PROHIBITION ON CONTRACTOR INVOLVEMENT WITH TERRORIST ACTIVITIES

The Contractor acknowledges that U.S. Executive Orders and Laws, including but not limited to E.O. 13224 and P.L. 107-56, prohibit transactions with, and the provision of resources and support to, individuals and organizations associated with terrorism. It is the legal responsibility of the Contractor to ensure compliance with these Executive Orders and Laws. This clause must be included in all subcontracts issued under this contract.

H.17. ACCESS TO DOCUMENTATION/DATA

The Government shall have physical and electronic access to all documentation and data generated under this contract, including: all data documenting Offeror performance; all data generated; all communications and correspondence with regulatory agencies and bodies to include all audit

observations, inspection reports, milestone completion documents, and all Offeror commitments and responses. Offeror shall provide the Government with an electronic copy of all correspondence with the FDA within 24 hours of receipt. The Government shall acquire unlimited rights to all data funded under a contract awarded in response to this RFP in accordance with FAR Subpart 27.4 and FAR Clause 52.227-14.

H.18. IN-PROCESS REVIEW

In Process Reviews (IPR) will be conducted at the discretion of the Government to discuss the progression of the milestones. The Government reserves the right to revise the milestones and budget pending program development status. Deliverables may be required when the IPRs are conducted. The Contractor's success in completing the required tasks under each work segment must be demonstrated through the Deliverables and Milestones specified under SECTION F. Those deliverables will constitute the basis for the Government's decision, at its sole discretion, to proceed with the work segment, or unilaterally institute changes to the work segment, or terminate the work segment. GO/NO GO Decision Gates may be negotiated with each awardee and included in SECTION F of any resultant contract.

IPRs may be scheduled at 12-month intervals, or at the discretion of the Government, to discuss progression of the contract. The Contractor shall provide a presentation following a prescribed template which will be provided by the Government at least 30 days prior to the IPR. The contractor shall provide a draft presentation to the Contracting Officer at least 10 days prior to the IPR.

H.19. IDENTIFICATION AND DISPOSITION OF DATA

The Contractor will be required to provide certain data generated under this contract to the Department of Health and Human Services (HHS). HHS reserves the right to review any other data determined by HHS to be relevant to this contract. The Contractor shall keep copies of all data required by the Food and Drug Administration (FDA) relevant to this contract for the time specified by the FDA.

H.20. DISSEMINATION OF INFORMATION

No information related to data obtained under this contract shall be released or publicized without the prior written notice to the Contracting Officer, whose response shall not be unreasonably withheld, conditioned, or delayed, provided that no such consent is required to comply with any law, rule, regulation, court ruling or similar order; for submission to any Government entity' for submission to any securities exchange on which the Offeror's (or its parent corporation's) securities may be listed for trading; or to third parties relating to securing, seeking, establishing or maintaining regulatory or other legal approvals or compliance, financing and capital raising activities, or mergers, acquisitions, or other business transactions.

PART II – CONTRACT CLAUSES

SECTION I – CONTRACT CLAUSES

FAR 52.252-2 Clauses Incorporated by Reference (Feb 1998)

This contract incorporates one or more clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available.

I.1. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR Chapter 1) CLAUSES

Full text of the FAR clauses may be accessed electronically at:
https://www.acquisition.gov/far/index.html

Reg	Clause	Date	Clause Title
FAR	52.202-1	Jan 2012	Definitions
FAR	52.203-3	Apr 1984	Gratuities
FAR	52.203-5	Apr 1984	Covenant Against Contingent Fees
FAR	52.203-6	Sep 2006	Restrictions on Subcontractor Sales to the Government
FAR	52.203-7	Oct 2010	Anti-Kickback Procedures
FAR	52.203-8	Jan 1997	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity
FAR	52.203-10	Jan 1997	Price or Fee Adjustment for Illegal or Improper Activity
FAR	52.203-12	Oct 2010	Limitation on Payments to Influence Certain Federal Transactions
FAR	52.203-13	Apr 2010	Contractor Code of Business Ethics and Conduct
FAR	52.203-14	Dec 2007	Display of Hotline Poster(s)
FAR	52.204-4	May 2011	Printed or Copied Double-Sided on Recycled Paper
FAR	52.204-7	Dec 2012	Central Contractor Registration
FAR	52.204-10	Aug 2012	Reporting Executive Compensation and First-Tier Subcontract Awards
FAR	52.209-6	Dec 2010	Protecting the Government's Interests When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment
FAR	52.215-2	Oct 2010	Audit and Records – Negotiation
FAR	52.215-8	Oct 1997	Order of Precedence - Uniform Contract Format
FAR	52.215-10	Aug 2011	Price Reduction for Defective Cost or Pricing Data
FAR	52.215-11	Aug 2011	Price Reduction for Defective Certified Cost or Pricing Data—Modifications.
FAR	52.215-12	Oct 2010	Subcontractor Cost or Pricing Data
FAR	52.215-15	Oct 2010	Pension Adjustments and Asset Reversions
FAR	52.215-18	Jul 2005	Reversion or Adjustment of Plans for Post-Retirement Benefits (PRB) other than Pensions
FAR	52.215-19	Oct 1997	Notification of Ownership Changes
FAR	52.215-21	Oct 2010	Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data – Modifications
FAR	52.215-23	Oct 2009	Limitations on Pass-Through Charges.
FAR	52.216-7	Jun 2011	Allowable Cost and Payment
FAR	52.216-8	Jun 2011	Fixed Fee
FAR	52.216-18	Oct 1995	Ordering
FAR	52.216-19	Oct 1995	Order Limitations
FAR	52.216-22	Oct 1995	Indefinite Quantity
FAR	52.216-27	Oct 1995	Single or Multiple Awards
FAR	52.217-8	Nov 1999	Option to Extend Services

FAR	52.217-9	Mar 2000	Option to Extend the Term of the Contract
FAR	52.219-8	Jan 2011	Utilization of Small Business Concerns
FAR	52.219-9	Jan 2011	Small Business Subcontracting Plan
FAR	52.219-16	Jan 1999	Liquidated Damages - Subcontracting Plan
FAR	52.219-25	Dec 2010	Small Disadvantaged Business Participation Program—Disadvantaged Status and Reporting.
FAR	52.222-2	Jul 1990	Payment for Overtime Premiums
FAR	52.222-3	June 2003	Convict Labor
FAR	52.222-21	Feb 1999	Prohibition of Segregated Facilities
FAR	52.222-26	Mar 2007	Equal Opportunity
FAR	52.222-29	Jun 2003	Notification of Visa Denial.
FAR	52.222-35	Sep 2010	Equal Opportunity for Veterans
FAR	52.222-36	Oct 2010	Affirmative Action for Workers with Disabilities
FAR	52.222-37	Sep 2010	Employment Reports on Veterans
FAR	52.222-38	Sep 2010	Compliance with Veterans' Employment Reporting Requirements
FAR	52.222-40	Dec 2010	Notification of Employee Rights Under the National Labor Relations Act
FAR	52.222-41	Nov 2007	Service Contract Act of 1965.
FAR	52.222-43	Sep 2009	Fair Labor Standards Act and Service Contract Act—Price Adjustment (Multiple Year and Option Contracts)
FAR	52.222-50	Feb 2009	Combating Trafficking in Persons
FAR	52.222-54	Jul 2012	Employment Eligibility Verification
FAR	52.223-6	May 2001	Drug-Free Workplace
FAR	52.223-18	Aug 2011	Encouraging Contractor Policy to Ban Text Messaging While Driving
FAR	52.225-13	Jun 2008	Restrictions on Certain Foreign Purchases
FAR	52.226-1	Jun 2000	Utilization of Indian Organizations and Indian-Owned Economic Enterprises.
FAR	52.227-1	Dec 2007	Authorization and Consent, Alternate 1
FAR	52.227-2	Dec 2007	Notice and Assistance Regarding Patent and Copyright Infringement
FAR	52.227-3	Apr 1984	Patent Indemnity
FAR	52.227-11	Dec 2007	Patent Rights—Ownership by the Contractor
FAR	52.227-14	Dec 2007	Rights in Data – General, Alternate II Completed portion as follows: Limited Rights Notice (Dec 2007) (a) These data are submitted with limited rights under Government Contract No._____ (and subcontract _____, if appropriate). These data may be reproduced and used by the Government with the express limitation that they will not, without written permission of the Contractor, be used for purposes of manufacture nor disclosed outside the Government; except that the Government may disclose these data outside the Government for the following purposes, provided that the Government makes such disclosure subject to prohibition against further use and disclosure: (i) Use (except for manufacture) by support service contractors. (ii) Evaluation by nongovernment evaluators. (b) This Notice shall be marked on any reproduction of these data, in whole or in part.
FAR	52.227-16	June 1987	Additional Data Requirements
FAR	52.229-3	Feb 2013	Federal, State and Local Taxes
FAR	52.232-1	Apr 1984	Payments
FAR	52.232-2	Apr 1984	Payments under Fixed-Price Research and Development Contracts

FAR	52.232-8	Feb 2002	Discounts for Prompt Payment
FAR	52.232-9	Apr 1984	Limitation on Withholding of Payments
FAR	52.232-11	Apr 1984	Extras
FAR	52.232-17	Oct 2010	Interest (Over the Simplified Acquisition Threshold)
FAR	52.232-20	Apr 1984	Limitation of Cost
FAR	52.232-23	Jan 1986	Assignment of Claims
FAR	52.232-25	Oct 2008	Prompt Payment
FAR	52.232-33	Oct 2003	Payment by Electronic Funds Transfer--Central Contractor Registration
FAR	52.233-1	Jul 2002	Disputes
FAR	52.233-3	Aug 1996	Protest After Award
FAR	52.233-4	Oct 2004	Applicable Law for Breach of Contract Claim
FAR	52.242-1	Apr 1984	Notice of Intent to Disallow Costs
FAR	52.242-3	May 2001	Penalties for Unallowable Costs
FAR	52.242-4	Jan 1997	Certification of Final Indirect Costs
FAR	52.242-13	Jul 1995	Bankruptcy
FAR	52.243-1	Aug 1987	Changes - Fixed-Price
FAR	52.243-2	Aug 1987	Changes—Cost-Reimbursement
FAR	52.243-6	Apr 1984	Change Order Accounting.
FAR	52.244-2	Oct 2010	Subcontracts, Alternate 1 (Jun 2007)
FAR	52.244-5	Dec 1996	Competition in Subcontracting
FAR	52.244-6	Dec 2010	Subcontracts for Commercial Items
FAR	52.245-1	Apr 2012	Government Property
FAR	52.245-9	Apr 2012	Use and Charges
FAR	52.246-23	Feb 1997	Limitation of Liability.
FAR	52.246-25	Feb 1997	Limitation of Liability—Services
FAR	52.249-2	Apr 2012	Termination for the Convenience of the Government (Fixed-Price)
FAR	52.249-6	May 2004	Termination (Cost-Reimbursement)
FAR	52.249-8	Apr 1984	Default (Fixed-Price Supply and Service)
FAR	52.249-9	Apr 1984	Default (Fixed-Price Research and Development)
FAR	52.249-14	Apr 1984	Excusable Delays
FAR	52.253-1	Jan 1991	Computer Generated Forms

I.2. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CFR Chapter 3) CLAUSES

Full text of the HHSAR clauses can be found at http://www.hhs.gov/oamp/policies/index.html

HHSAR	352.201-70	Jan 2006	Paperwork Reduction Act
HHSAR	352.202-1	Jan 2006	Definitions - with Alternate paragraph (h)
HHSAR	352.203-70	Mar 2012	Anti-Lobbying
HHSAR	352.215-70	Jan 2006	Late Proposals and Revisions
HHSAR	352.216-70	Jan 2006	Additional Cost Principles
HHSAR	352.222-70	Jan 2010	Contractor Cooperation in Equal Employment Opportunity Investigations
HHSAR	352.223-70	Jan 2006	Safety and Health
HHSAR	352.224-70	Jan 2006	Privacy Act
HHSAR	352.227-70	Jan 2006	Publications and Publicity
HHSAR	352.228-7	Dec 1991	Insurance - Liability to Third Persons
HHSAR	352.231-71	Jan 2001	Pricing of Adjustments

HHSAR	352.233-71	Jan 2006	Litigation and Claims
HHSAR	352.242-70	Jan 2006	Key Personnel
HHSAR	352.242-73	Jan 2006	Withholding of Contract Payments
HHSAR	352.242-74	Apr 1984	Final Decisions on Audit Findings
HHSAR	352.270-4	Jan 2006	Protection of Human Subjects
HHSAR	352.270-6	Jan 2006	Restriction on use of Human Subjects

I.3. ADDITIONAL CONTRACT CLAUSES

I.3.1. Additional HHS Acquisition Regulation (HHSAR) Clauses – In Full Text

352.231-70 Salary rate limitation (August 2012)

1. Pursuant to the current and applicable prior HHS appropriations acts, the Contractor shall not use contract funds to pay the direct salary of an individual at a rate in excess of the Federal Executive Schedule Level II in effect on the date an expense is incurred.
2. For purposes of the salary rate limitation, the terms ``direct salary,'' ``salary'', and ``institutional base salary'', have the same meaning and are collectively referred to as ``direct salary'', in this clause. An individual's direct salary is the annual compensation that the Contractor pays for an individual's direct effort (costs) under the contract. Direct salary excludes any income that an individual may be permitted to earn outside of duties to the Contractor. Direct salary also excludes fringe benefits, overhead, and general and administrative expenses (also referred to as indirect costs or facilities and administrative [F&A] costs).

Note: The salary rate limitation does not restrict the salary that an organization may pay an individual working under an HHS contract or order; it merely limits the portion of that salary that may be paid with Federal funds.

1. The salary rate limitation also applies to individuals under subcontracts. If this is a multiple-year contract or order, it may be subject to unilateral modification by the Contracting Officer to ensure that an individual is not paid at a rate that exceeds the salary rate limitation provision established in the HHS appropriations act in effect when the expense is incurred regardless of the rate initially used to establish contract or order funding.
2. See the salaries and wages pay tables on the U.S. Office of Personnel Management Web site for Federal Executive Schedule salary levels that apply to the current and prior periods.

I.3.2. Additional Federal Acquisition Regulation (FAR) (48 CFR Chapter 1) Clauses – In Full Text

52.209-9 Updates of Publicly Available Information Regarding Responsibility Matters (Feb 2012)

(a) The Contractor shall update the information in the Federal Awardee Performance and Integrity Information System (FAPIIS) on a semi-annual basis, throughout the life of the contract, by posting the required information in the Central Contractor Registration database via https://www.acquisition.gov.

(b) As required by section 3010 of the Supplemental Appropriations Act, 2010 (Pub. L. 111-212), all information posted in FAPIIS on or after April 15, 2011, except past performance reviews, will be publicly available. FAPIIS consists of two segments—

(1) The non-public segment, into which Government officials and the Contractor post information, which can only be viewed by—

(i) Government personnel and authorized users performing business on behalf of the Government; or

(ii) The Contractor, when viewing data on itself; and

(2) The publicly-available segment, to which all data in the non-public segment of FAPIIS is automatically transferred after a waiting period of 14 calendar days, except for—

(i) Past performance reviews required by subpart 42.15;

(ii) Information that was entered prior to April 15, 2011; or

(iii) Information that is withdrawn during the 14-calendar-day waiting period by the Government official who posted it in accordance with paragraph (c)(1) of this clause.

(c) The Contractor will receive notification when the Government posts new information to the Contractor's record.

(1) If the Contractor asserts in writing within 7 calendar days, to the Government official who posted the information, that some of the information posted to the non-public segment of FAPIIS is covered by a disclosure exemption under the Freedom of Information Act, the Government official who posted the information must within 7 calendar days remove the posting from FAPIIS and resolve the issue in accordance with agency Freedom of Information procedures, prior to reposting the releasable information. The contractor must cite 52.209-9 and request removal within 7 calendar days of the posting to FAPIIS.

(2) The Contractor will also have an opportunity to post comments regarding information that has been posted by the Government. The comments will be retained as long as the associated information is retained, *i.e.*, for a total period of 6 years. Contractor comments will remain a part of the record unless the Contractor revises them.

(3) As required by section 3010 of Pub. L. 111-212, all information posted in FAPIIS on or after April 15, 2011, except past performance reviews, will be publicly available.

(d) Public requests for system information posted prior to April 15, 2011, will be handled under Freedom of Information Act procedures, including, where appropriate, procedures promulgated under E.O. 12600.

52.216-18 Ordering (Oct 1995) ***(To be completed at the time of award)***

(a) Any supplies and services to be furnished under this contract shall be ordered by issuance of delivery orders or task orders by the individuals or activities designated in the Schedule. Such orders may be issued from _____ to _____.

(b) All delivery orders or task orders are subject to the terms and conditions of this contract. In the event of conflict between a delivery order or task order and this contract, the contract shall control.

(c) If mailed, a delivery order or task order is considered "issued" when the Government deposits the order in the mail. Orders may be issued orally, by facsimile, or by electronic commerce methods only if authorized in the Schedule.

(End of clause)

52.216-19 Order Limitations (Oct 1995) ***(To be completed at the time of award)***

(a) Minimum order. When the Government requires supplies or services covered by this contract in an amount of less than **TBD**, the Government is not obligated to purchase, nor is the Contractor obligated to furnish, those supplies or services under the contract.

(b) Maximum order. The Contractor is not obligated to honor—

(1) Any order for a single item in excess of **TBD**;

(2) Any order for a combination of items in excess of **TBD**; or

(3) A series of orders from the same ordering office within **7 days** that together call for quantities exceeding the limitation in paragraph (b)(1) or (2) of this section.

(c) If this is a requirements contract (i.e., includes the Requirements clause at subsection 52.216-21 of the Federal Acquisition Regulation (FAR)), the Government is not required to order a part of any one requirement from the Contractor if that requirement exceeds the maximum-order limitations in paragraph (b) of this section.

(d) Notwithstanding paragraphs (b) and (c) of this section, the Contractor shall honor any order exceeding the maximum order limitations in paragraph (b), unless that order (or orders) is returned to the ordering office **within 2 days** after Contractor receives the order, with written notice stating the Contractor's intent not to ship the item (or items) called for and the reasons. Upon receiving this notice, the Government may acquire the supplies or services from another source.

(End of clause)

52.216-22 Indefinite Quantity (Oct 1995)

(a) This is an indefinite-quantity contract for the supplies or services specified, and effective for the period stated, in the Schedule. The quantities of supplies and services specified in the Schedule are estimates only and are not purchased by this contract.

(b) Delivery or performance shall be made only as authorized by orders issued in accordance with the Ordering clause. The Contractor shall furnish to the Government, when and if ordered, the supplies or services specified in the Schedule up to and including the quantity designated in the Schedule as the "maximum." The Government shall order at least the quantity of supplies or services designated in the Schedule as the "minimum."

(c) Except for any limitations on quantities in the Order Limitations clause or in the Schedule, there is no limit on the number of orders that may be issued. The Government may issue orders requiring delivery to multiple destinations or performance at multiple locations.

(d) Any order issued during the effective period of this contract and not completed within that period shall be completed by the Contractor within the time specified in the order. The contract shall govern the Contractor's and Government's rights and obligations with respect to that order to the same extent as if the order were completed during the contract's effective period; provided, that the Contractor shall not be required to make any deliveries under this contract after the effective date of the contract.

(End of clause)

52.222-2 Payment for Overtime Premiums (JUL 1990)

(a) The use of overtime is authorized under this contract if the overtime premium does not exceed $0 or the overtime premium is paid for work -

(1) Necessary to cope with emergencies such as those resulting from accidents, natural disasters, breakdowns of production equipment, or occasional production bottlenecks of a sporadic nature;

(2) By indirect-labor employees such as those performing duties in connection with administration, protection, transportation, maintenance, standby plant protection, operation of utilities, or accounting;

(3) To perform tests, industrial processes, laboratory procedures, loading or unloading of transportation conveyances, and operations in flight or afloat that are continuous in nature and cannot reasonably be interrupted or completed otherwise; or

(4) That will result in lower overall costs to the Government.

(b) Any request for estimated overtime premiums that exceeds the amount specified above shall include all estimated overtime for contract completion and shall -

(1) Identify the work unit; *e.g.*, department or section in which the requested overtime will be used, together with present workload, staffing, and other data of the affected unit sufficient to permit the Contracting Officer to evaluate the necessity for the overtime;
(2) Demonstrate the effect that denial of the request will have on the contract delivery or performance schedule;
(3) Identify the extent to which approval of overtime would affect the performance or payments in connection with other Government contracts, together with identification of each affected contract; and
(4) Provide reasons why the required work cannot be performed by using multishift operations or by employing additional personnel.

52.227-11 Patent Rights--Ownership by the Contractor (DEC 2007)

(a) As used in this clause--

"Invention" means any invention or discovery that is or may be patentable or otherwise protectable under title 35 of the U.S. Code, or any variety of plant that is or may be protectable under the Plant Variety Protection Act (7 U.S.C. 2321, et seq.)

"Made" means--

(1) When used in relation to any invention other than a plant variety, the conception or first actual reduction to practice of the invention; or
(2) When used in relation to a plant variety, that the Contractor has at least tentatively determined that the variety has been reproduced with recognized characteristics.

"Nonprofit organization" means a university or other institution of higher education or an organization of the type described in section 501(c)(3) of the Internal Revenue Code of 1954 (26 U.S.C. 501(c)) and exempt from taxation under section 501(a) of the Internal Revenue Code (26 U.S.C. 501(a)), or any nonprofit scientific or educational organization qualified under a State nonprofit organization statute.

"Practical application" means to manufacture, in the case of a composition of product; to practice, in the case of a process or method; or to operate, in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is being utilized and that its benefits are, to the extent permitted by law or Government regulations, available to the public on reasonable terms.

"Subject invention" means any invention of the Contractor made in the performance of work under this contract.

(b) Contractor's rights.
(1) Ownership. The Contractor may retain ownership of each subject invention throughout the world in accordance with the provisions of this clause.

(2) License.

(i) The Contractor shall retain a nonexclusive royalty-free license throughout the world in each subject invention to which the Government obtains title, unless the Contractor fails to disclose the invention within the times specified in paragraph (c) of this clause. The Contractor's license extends to any domestic subsidiaries and affiliates within the corporate structure of which the Contractor is a part, and includes the right to grant sublicenses to the extent the Contractor was legally obligated to do so at contract award. The license is transferable only with the written approval of the agency, except when transferred to the successor of that part of the Contractor's business to which the invention pertains.

(ii) The Contractor's license may be revoked or modified by the agency to the extent necessary to achieve expeditious practical application of the subject invention in a particular country in accordance with the procedures in FAR 27.302(i)(2) and 27.304-1(f).

(c) Contractor's obligations. (1) The Contractor shall disclose in writing each subject invention to the Contracting Officer within 2 months after the inventor discloses it in writing to Contractor personnel responsible for patent matters. The disclosure shall identify the inventor(s) and this contract under which the subject invention was made. It shall be sufficiently complete in technical detail to convey a clear understanding of the subject invention. The disclosure shall also identify any publication, on sale (i.e., sale or offer for sale), or public use of the subject invention, or whether a manuscript describing the subject invention has been submitted for publication and, if so, whether it has been accepted for publication. In addition, after disclosure to the agency, the Contractor shall promptly notify the Contracting Officer of the acceptance of any manuscript describing the subject invention for publication and any on sale or public use.

(2) The Contractor shall elect in writing whether or not to retain ownership of any subject invention by notifying the Contracting Officer within 2 years of disclosure to the agency. However, in any case where publication, on sale, or public use has initiated the 1-year statutory period during which valid patent protection can be obtained in the United States, the period for election of title may be shortened by the agency to a date that is no more than 60 days prior to the end of the statutory period.

(3) The Contractor shall file either a provisional or a nonprovisional patent application or a Plant Variety Protection Application on an elected subject invention within 1 year after election. However, in any case where a publication, on sale, or public use has initiated the 1-year statutory period during which valid patent protection can be obtained in the United States, the Contractor shall file the application prior to the end of that statutory period. If the Contractor files a provisional application, it shall file a nonprovisional application within 10 months of the filing of the provisional application. The Contractor shall file patent applications in additional countries or international patent offices within either 10 months of the first filed patent application (whether provisional or nonprovisional) or 6 months from the date permission is granted by the Commissioner of Patents to file foreign patent applications where such filing has been prohibited by a Secrecy Order.

(4) The Contractor may request extensions of time for disclosure, election, or filing under paragraphs (c)(1), (c)(2), and (c)(3) of this clause.

(d) Government's rights--(1) Ownership. The Contractor shall assign to the agency, on written request, title to any subject invention--

(i) If the Contractor fails to disclose or elect ownership to the subject invention within the times specified in paragraph (c) of this clause, or elects not to retain ownership; provided, that the agency may request title only within 60 days after learning of the Contractor's failure to disclose or elect within the specified times.

(ii) In those countries in which the Contractor fails to file patent applications within the times specified in paragraph (c) of this clause; provided, however, that if the Contractor has filed a patent application in a country after the times specified in paragraph (c) of this clause, but prior to its receipt of the written request of the agency, the Contractor shall continue to retain ownership in that country.

(iii) In any country in which the Contractor decides not to continue the prosecution of any application for, to pay the maintenance fees on, or defend in reexamination or opposition proceeding on, a patent on a subject invention.

(2) License. If the Contractor retains ownership of any subject invention, the Government shall have a nonexclusive, nontransferable, irrevocable, paid-up license to practice, or have practiced for or on its behalf, the subject invention throughout the world.

(e) Contractor action to protect the Government's interest. (1) The Contractor shall execute or have executed and promptly deliver to the agency all instruments necessary to--

(i) Establish or confirm the rights the Government has throughout the world in those subject inventions in which the Contractor elects to retain ownership; and
(ii) Assign title to the agency when requested under paragraph (d) of this clause and to enable the Government to obtain patent protection and plant variety protection for that subject invention in any country.

(2) The Contractor shall require, by written agreement, its employees, other than clerical and nontechnical employees, to disclose promptly in writing to personnel identified as responsible for the administration of patent matters and in the Contractor's format, each subject invention in order that the Contractor can comply with the disclosure provisions of paragraph (c) of this clause, and to execute all papers necessary to file patent applications on subject inventions and to establish the Government's rights in the subject inventions. The disclosure format should require, as a minimum, the information required by paragraph (c)(1) of this clause. The Contractor shall instruct such employees, through employee agreements or other suitable educational programs, as to the importance of reporting inventions in sufficient time to permit the filing of patent applications prior to U.S. or foreign statutory bars.

(3) The Contractor shall notify the Contracting Officer of any decisions not to file a nonprovisional patent application, continue the prosecution of a patent application, pay maintenance fees, or defend in a reexamination or opposition proceeding on a patent, in any country, not less than 30 days before the expiration of the response or filing period required by the relevant patent office.

(4) The Contractor shall include, within the specification of any United States nonprovisional patent or plant variety protection application and any patent or plant variety protection certificate issuing thereon covering a subject invention, the following statement, "This invention was made with Government support under (identify the contract) awarded by (identify the agency). The Government has certain rights in the invention."

(f) Reporting on utilization of subject inventions. The Contractor shall submit, on request, periodic reports no more frequently than annually on the utilization of a subject invention or on efforts at obtaining utilization of the subject invention that are being made by the Contractor or its licensees or assignees. The reports shall include information regarding the status of development, date of first commercial sale or use, gross royalties received by the Contractor, and other data and information as the agency may reasonably specify. The Contractor also shall provide additional reports as may be requested by the agency in connection with any march-in proceeding undertaken by the agency in accordance with paragraph (h) of this clause. The Contractor also shall mark any utilization report as confidential/proprietary to help prevent inadvertent release outside the Government. As required by 35 U.S.C. 202(c)(5), the agency will not disclose that information to persons outside the Government without the Contractor's permission.

(g) Preference for United States industry. Notwithstanding any other provision of this clause, neither the Contractor nor any assignee shall grant to any person the exclusive right to use or sell any subject invention in the United States unless the person agrees that any products embodying the subject invention or produced through the use of the subject invention will be manufactured substantially in the United States. However, in individual cases, the requirement for an agreement may be waived by the agency upon a showing by the Contractor or its assignee that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States, or that under the circumstances domestic manufacture is not commercially feasible.

(h) March-in rights. The Contractor acknowledges that, with respect to any subject invention in which it has retained ownership, the agency has the right to require licensing pursuant to 35 U.S.C. 203 and 210(c), and in accordance with the procedures in 37 CFR 401.6 and any supplemental regulations of the agency in effect on the date of contract award.

(i) Special provisions for contracts with nonprofit organizations. If the Contractor is a nonprofit organization, it shall--

(1) Not assign rights to a subject invention in the United States without the written approval of the agency, except where an assignment is made to an organization that has as one of its primary functions the management of inventions, provided, that the assignee shall be subject to the same provisions as the Contractor;

(2) Share royalties collected on a subject invention with the inventor, including Federal employee co-inventors (but through their agency if the agency deems it appropriate) when the subject invention is assigned in accordance with 35 U.S.C. 202(e) and 37 CFR 401.10;

(3) Use the balance of any royalties or income earned by the Contractor with respect to subject inventions, after payment of expenses (including payments to inventors)

incidental to the administration of subject inventions for the support of scientific research or education; and

(4) Make efforts that are reasonable under the circumstances to attract licensees of subject inventions that are small business concerns, and give a preference to a small business concern when licensing a subject invention if the Contractor determines that the small business concern has a plan or proposal for marketing the invention which, if executed, is equally as likely to bring the invention to practical application as any plans or proposals from applicants that are not small business concerns; provided, that the Contractor is also satisfied that the small business concern has the capability and resources to carry out its plan or proposal. The decision whether to give a preference in any specific case will be at the discretion of the Contractor.

(5) Allow the Secretary of Commerce to review the Contractor's licensing program and decisions regarding small business applicants, and negotiate changes to its licensing policies, procedures, or practices with the Secretary of Commerce when the Secretary's review discloses that the Contractor could take reasonable steps to more effectively implement the requirements of paragraph (i)(4) of this clause.

(j) Communications. Shall be addressed to the Contracting Officer.

(k) Subcontracts.

(1) The Contractor shall include the substance of this clause, including this paragraph (k), in all subcontracts for experimental, developmental, or research work to be performed by a small business concern or nonprofit organization.

(2) The Contractor shall include in all other subcontracts for experimental, developmental, or research work the substance of the patent rights clause required by FAR Subpart 27.3.

(3) At all tiers, the patent rights clause must be modified to identify the parties as follows: references to the Government are not changed, and the subcontractor has all rights and obligations of the Contractor in the clause. The Contractor shall not, as part of the consideration for awarding the subcontract, obtain rights in the subcontractor's subject inventions.

(4) In subcontracts, at any tier, the agency, the subcontractor, and the Contractor agree that the mutual obligations of the parties created by this clause constitute a contract between the subcontractor and the agency with respect to the matters covered by the clause; provided, however, that nothing in this paragraph is intended to confer any jurisdiction under the Contract Disputes Act in connection with proceedings under paragraph (h) of this clause.

PART III – ATTACHMENTS

SECTION J – LIST OF ATTACHMENTS

The following Attachments are provided with this Solicitation:

1. Sample Request for Task Order Response 0001
2. Sample Request for Task Order Response 0002
3. SF-LLL, Disclosure of Lobbying Activities, with instructions (http://www.whitehouse.gov/omb/grants/sflllin.pdf)
4. Small Business Subcontracting Plan (http://www.hhs.gov/osdbu/forms.html)
5. Protection of Human Subjects
6. Offeror's Points of Contact
7. Invoice Instructions for Cost Reimbursement Contracts
8. Invoice Instructions for Fixed Price Contracts
9. Risk Mitigation Plan/ Matrix Template
10. Contract Performance Evaluation Report
11. Past Performance Questionnaire
12. Summary of Related Activities
13. ACH Vendor/ Miscellaneous Payment Enrollment Form

SECTION K – REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS

NOTE: IF YOU INTEND TO SUBMIT A PROPOSAL, YOU SHALL:

1. Complete the Online Representations and Certifications Application (ORCA) at website https://www.sam.gov or http://www.bpn.gov/

2. Complete this Section and include it as part of your BUSINESS PROPOSAL.

If you are unable to access any documents electronically, you may request a copy from the Contracting Officer identified on the cover page of this solicitation.

K.1. FAR 52.204-8 ANNUAL REPRESENTATIONS AND CERTIFICATIONS (DEC 2012)

(a)(1) The North American Industry Classification System (NAICS) code for this acquisition is _____ [*insert NAICS code*].
(2) The small business size standard is _____ [*insert size standard*].
(3) The small business size standard for a concern which submits an offer in its own name, other than on a construction or service contract, but which proposes to furnish a product which it did not itself manufacture, is 500 employees.
(b)(1) If the clause at 52.204-7, Central Contractor Registration, is included in this solicitation, paragraph (d) of this provision applies.
(2) If the clause at 52.204-7 is not included in this solicitation, and the Offeror is currently registered in CCR, and has completed the ORCA electronically, the Offeror may choose to use paragraph (d) of this provision instead of completing the corresponding individual representations and certifications in the solicitation. The Offeror shall indicate which option applies by checking one of the following boxes:
[ ] (i) Paragraph (d) applies.
[ ] (ii) Paragraph (d) does not apply and the Offeror has completed the individual representations and certifications in the solicitation.
(c)(1) The following representations or certifications in ORCA are applicable to this solicitation as indicated:

(i) 52.203-2, Certificate of Independent Price Determination. This provision applies to solicitations when a firm-fixed-price contract or fixed-price contract with economic price adjustment is contemplated, unless—

(A) The acquisition is to be made under the simplified acquisition procedures in Part 13;

(B) The solicitation is a request for technical proposals under two-step sealed bidding procedures; or

(C) The solicitation is for utility services for which rates are set by law or regulation.

(ii) 52.203-11, Certification and Disclosure Regarding Payments to Influence Certain Federal Transactions. This provision applies to solicitations expected to exceed $150,000.

(iii) 52.204-3, Taxpayer Identification. This provision applies to solicitations that do not Include the clause at 52.204-7, Central Contractor Registration.

(iv) 52.204-5, Women-Owned Business (Other Than Small Business). This provision applies to solicitations that—

(A) Are not set aside for small business concerns;

(B) Exceed the simplified acquisition threshold; and

(C) Are for contracts that will be performed in the United States or its outlying areas.

(v) 52.209-2, Prohibition on Contracting with Inverted Domestic Corporations—Representation. This provision applies to solicitations using funds appropriated in fiscal years 2008, 2009, 2010, or 2012.

(vi) 52.209-5, Certification Regarding Responsibility Matters. This provision applies to solicitations where the contract value is expected to exceed the simplified acquisition threshold.

(vii) 52.214-14, Place of Performance—Sealed Bidding. This provision applies to invitations for bids except those in which the place of performance is specified by the Government.

(viii) 52.215-6, Place of Performance. This provision applies to solicitations unless the place of performance is specified by the Government.

(ix) 52.219-1, Small Business Program Representations (Basic & Alternate I). This provision applies to solicitations when the contract will be performed in the United States or its outlying areas.

(A) The basic provision applies when the solicitations are issued by other than DoD, NASA, and the Coast Guard.

(B) The provision with its Alternate I applies to solicitations issued by DoD, NASA, or the Coast Guard.

(x) 52.219-2, Equal Low Bids. This provision applies to solicitations when contracting by sealed bidding and the contract will be performed in the United States or its outlying areas.

(xi) 52.222-22, Previous Contracts and Compliance Reports. This provision applies to solicitations that include the clause at 52.222-26, Equal Opportunity.

(xii) 52.222-25, Affirmative Action Compliance. This provision applies to solicitations, other than those for construction, when the solicitation includes the clause at 52.222-26, Equal Opportunity.

(xiii) 52.222-38, Compliance with Veterans' Employment Reporting Requirements. This provision applies to solicitations when it is anticipated the contract award will exceed the simplified acquisition threshold and the contract is not for acquisition of commercial items.

(xiv) 52.223-1, Biobased Product Certification. This provision applies to solicitations that require the delivery or specify the use of USDA–designated items; or include the clause at 52.223-2, Affirmative Procurement of Biobased Products Under Service and Construction Contracts.

(xv) 52.223-4, Recovered Material Certification. This provision applies to solicitations that are for, or specify the use of, EPA–designated items.

(xvi) 52.225-2, Buy American Act Certificate. This provision applies to solicitations containing the clause at 52.225-1.

(xvii) 52.225-4, Buy American Act—Free Trade Agreements—Israeli Trade Act Certificate. (Basic, Alternates I, II, and III.) This provision applies to solicitations containing the clause at 52.225-3.

(A) If the acquisition value is less than $25,000, the basic provision applies.

(B) If the acquisition value is $25,000 or more but is less than $50,000, the provision with its Alternate I applies.

(C) If the acquisition value is $50,000 or more but is less than $77,494, the provision with its Alternate II applies.

(D) If the acquisition value is $77,494 or more but is less than $100,000, the provision with its Alternate III applies.

(xviii) 52.225-6, Trade Agreements Certificate. This provision applies to solicitations containing the clause at 52.225-5.

(xix) 52.225-20, Prohibition on Conducting Restricted Business Operations in Sudan—Certification. This provision applies to all solicitations.

(xx) 52.225-25, Prohibition on Contracting with Entities Engaging in Certain Activities or Transactions Relating to Iran-Representation and Certifications. This provision applies to all solicitations.

(xxi) 52.226-2, Historically Black College or University and Minority Institution Representation. This provision applies to—

(A) Solicitations for research, studies, supplies, or services of the type normally acquired from higher educational institutions; and

(B) For DoD, NASA, and Coast Guard acquisitions, solicitations that contain the clause at 52.219-23, Notice of Price Evaluation Adjustment for Small Disadvantaged Business Concerns.

(2) The following certifications are applicable as indicated by the Contracting Officer:
[*Contracting Officer check as appropriate.*]

__ (i) 52.219-22, Small Disadvantaged Business Status.

__ (A) Basic.

__ (B) Alternate I.

__ (ii) 52.222-18, Certification Regarding Knowledge of Child Labor for Listed End Products.

__ (iii) 52.222-48, Exemption from Application of the Service Contract Act to Contracts for Maintenance, Calibration, or Repair of Certain Equipment Certification.

__ (iv) 52.222-52, Exemption from Application of the Service Contract Act to Contracts for Certain Services–Certification.

__ (v) 52.223-9, with its Alternate I, Estimate of Percentage of Recovered Material Content for EPA–Designated Products (Alternate I only).

__ (vi) 52.227-6, Royalty Information.

__ (A) Basic.

__(B) Alternate I.

__ (vii) 52.227-15, Representation of Limited Rights Data and Restricted Computer Software.

(d) The Offeror has completed the annual representations and certifications electronically via the Online Representations and Certifications Application (ORCA) website accessed through https://www.acquisition.gov. After reviewing the ORCA database information, the Offeror verifies by submission of the offer that the representations and certifications currently posted electronically that apply to this solicitation as indicated in paragraph (c) of this provision have been entered or updated within the last 12 months, are current, accurate, complete, and applicable to this solicitation (including the business size standard applicable to the NAICS code referenced for this solicitation), as of the date of this offer and are incorporated in this offer by reference (see FAR 4.1201); except for the changes identified below [*Offeror to insert changes, identifying change by clause number, title, date*]. These amended representation(s) and/or certification(s) are also incorporated in this offer and are current, accurate, and complete as of the date of this offer.

FAR Clause #	Title	Date	Change
_____	_____	_____	_____

Any changes provided by the Offeror are applicable to this solicitation only, and do not result in an update to the representations and certifications posted on ORCA.

(End of provision)

SECTION L – INSTRUCTIONS, CONDITIONS AND NOTICES TO OFFERORS

L.1. PACKAGING AND DELIVERY OF PROPOSAL:

(a) Offerors are invited to submit a proposal in response to this solicitation. All proposals received will become part of the official file.

(b) The following instructions establish the acceptable minimum requirements for the format and content of proposals.

(c) The proposal must be signed by an official authorized to bind the Offeror(s) organization and must stipulate that it is predicated upon all the terms and conditions of this RFP.

The proposal must be prepared in two parts: a "Technical Proposal" and a "Business Proposal." Each of the parts shall be separate and complete in itself so that evaluation of one may be accomplished independently of, and concurrently with, evaluation of the other. Proposals will be paginated and shall be legible. Pages shall be numbered consecutively starting with page 1. Pages shall be single-spaced, 8.5 by 11 inch paper of 10- or 12-point font.

PACKAGING AND DELIVERY OF PROPOSAL: Proposals must be submitted in Adobe PDF, Microsoft Word, Microsoft Excel, and Microsoft Project 2007 electronic format as appropriate and sent via e-mail to MCM-CSN@hhs.gov no later than May 16, 2013 – 12 pm ET. Facsimile proposals are **not** authorized.

To expedite the proposal evaluation, all documents required for responding to the RFP should be placed in the following order:

1. COVER PAGE
Include RFP title, number, name of organization, DUNS No., identification of the proposal part, and indicate whether the proposal is an original or a copy.

2. TECHNICAL PROPOSAL
It is recommended that the technical proposal consist of a cover page, a table of contents, and the information requested in the SOO. Appendices may be provided with the technical proposal, with the appropriate tabs.

3. BUSINESS PROPOSAL
It is recommended that the business proposal consist of a cover page, a table of contents, and the information requested in the SOO associating cost with identified task. The business proposal shall include the business portion of the Offeror’s response to Sample Request for Task Order Response 0001 and Sample Request for Task Order Response 0002.

L.2. TECHNICAL PROPOSAL

L.2.1. Technical Proposal Instructions

Offerors shall prepare their technical proposal submissions to respond to the requirements listed in SECTION C, and shall provide an index that cross-links the proposal with SECTION C and Evaluation Factors in SECTION M.

The technical proposal should reflect a clear understanding of the nature of the work being undertaken. The technical proposal must include information on capabilities of the Offeror and a Statement of Work to respond to the Government's requirements as defined in the Statement of Objectives. At minimum, Offerors should address how the project is to be organized, staffed, and managed. Information should be provided with sufficient detail to demonstrate your ability to understand and manage important events and tasks. The Offeror must submit a detailed explanation of the proposed technical approach in conjunction with the tasks to be performed in achieving the project objectives. Proposals which merely offer to conduct a program in accordance with the objectives of the USG will not be eligible for award.

To aid in the evaluation of responses to Objectives 1 and 2, Sample Task Orders 0001 and 0002 (respectively) have been provided. A detailed sample response must be submitted indicating how the work described in Sample Request for Task Order Response 0001 (Attachment 1) and Sample Request for Task Order Response 0002 (Attachment 2) is to be accomplished. The technical approach should be in as much detail as is necessary to fully explain the proposed technical approach or method. Visual aids and diagrams are encouraged. Proposals that insufficiently detail how the Government's objectives will be met in their proposed work plan/statement of work will not receive a favorable technical evaluation.

A proposal to address the objectives of Sample RTOR 0001 at minimum should include Technical and Business volumes. References to information provided in response to this RFP can be used to limit the amount of redundant information. Important assumptions made by the Offeror about the study should be itemized separately. Key personnel should be clearly identified. The business volume should be complete.

A plan to manage the 'Preparedness' and 'Response' components of Sample RTOR 0002 should clearly identify those tasks that are required as part of the preparation for a response within the timeframe indicated. Requirements of the respondent to execute the scope requested within the timeframe indicated should be itemized. Demonstration of previous experience and capability to provide additional and unique core services such as live agent challenge clinical studies is desired.

The technical proposal may not exceed 75 pages. The appendix of the technical proposal may not exceed 50 pages.

Proposals will be technically evaluated in accordance with the merit rating factors and confidence ratings as described in the final RFP. The technical evaluation is conducted in accordance with the technical evaluation criteria in SECTION M by a technical review panel. This evaluation produces color code/adjective ratings which are based upon the information contained in the Offeror's proposal.

As part of the technical proposal, the Offeror's will be required to submit a cross reference between the RFP and technical proposal to assist the government in their review.

It is strongly recommended that Offerors use the following template as the Table of Contents for the Technical Proposal. All information presented in the technical proposal should be presented in the order specified below.

L.2.1.1. Technical Proposal – Components

(1) Section 1: Front Matter

Proposal Title Page. Include RFP title, number, name of organization and DUNs number.

Government notice for handling of proposals

Table of Contents

(2) Section 2: Technical Proposal Overview

(Suggested 3-page maximum – included in total page limitation)

Provide a brief overview of the Technical Proposal, including the following:

A. A brief description of activities to be performed by the Offeror and all proposed subcontractors, including identification of all proposed subcontractors and a list of key personnel for the Offeror and the proposed subcontractors with degrees, titles and role within the project. A summary of staff expertise including the total number trained, number available to be assigned to this contract for the Offeror and all proposed subcontractors, and the total number of additional staff to be hired and trained.

B. The key features of the proposed reporting systems for safety monitoring and for tracking and reporting on operations and management support activities.

C. The facilities and equipment to be made available by the Offeror and all proposed subcontractors

(3) Section 3: Mandatory Evaluation Criteria

Offerors must show completion of at least one infectious disease or chemical, biological, radiological or nuclear clinical study under a FDA Investigational New Drug (IND) application in the last 5 years in order to be considered for award. Offerors shall submit the title of the clinical study, the identity of the sponsor, the IND number as documentation.

(4) Section 4: Statement of Work

A detailed statement of work must be submitted as a separate section in the technical proposal indicating how each aspect of the Government's Statement of Objectives in SECTION C is to be accomplished. Your management/technical approach should be in as much detail as you consider necessary to fully explain your proposed technical approach/

method. The technical proposal should reflect a clear understanding of the nature of the work being undertaken. The technical proposal must include information on how the project is to be organized, staffed, and managed. Information should be provided which will demonstrate your ability to understand and manage important events and tasks.

(5) Section 5: Technical Evaluation Criteria

A. Technical Plan/Approach

Objective 1: Clinical Studies

For each item in Objective 1, maintaining the same outline, describe in detail and document relevant organizational experience with the subject of the each item and subheadings. As appropriate describe issues or obstacles encountered in the provision of those services or products and discuss approaches implemented that corrected them. As appropriate describe risk management practices to identify root causes of risks and implement strategies to mitigate those risks.

Objective 2: Clinical Trial Response Readiness

Describe in detail the method by which the Offeror will create a management plan to prepare for and execute a clinical study described in the timeframe indicated. This plan should detail the activities that must be completed prior to study execution, activities required to maintain readiness capability and include a clear, executable process for initiating the study within the timeframe required.

B. Organizational Experience and Competency

Provide a review of the Offeror's relevant experience and competency in Project Management, Relevant Experience, Data Management and Quality Management.

C. Personnel Qualifications

List Key Personnel and describe individual training and contributions in previous clinical programs relevant to this statement of objectives. Describe the successful CRO leadership of similar magnitude and scope projects. Staff continuity and or staff turnover metrics should also be presented. A resume should be included in the appendix for key personnel (maximum 2-pages per person).

D. Program and Risk Management Plan

Describe in sufficient detail a comprehensive plan outlining the Offeror's approach to program and risk management.

E. Sample Request for Task Order Response 0001

Describe in detail the Offeror's plan to prepare for and execute a clinical study described, in the timeframe indicated. The Offeror shall submit a Gantt chart presented electronically as an integrated project plan in Microsoft Project 2007 format. The Gantt chart must contain sufficient detail to permit reviewers to make a realistic evaluation of the Offeror's likelihood of success. The Gantt chart should contain and track to a Work Breakdown Structure (WBS). The Gantt chart should

show successors and predecessors, and milestones. The Offeror shall submit an Integrated Project Plan that outlines key, critical path milestones, with "go/no go" decision criteria (entrance and exit criteria for each phase of the project). The project plan should include, but not be limited to, milestones in manufacturing, regulatory submissions, and storage and delivery of product.

The business portion of the Offeror's response to Sample Request for Task Order Response 0001 shall be limited to 15 pages and shall be included in the Offeror's business proposal as described in SECTION L.3.

F. Sample Request for Task Order Response 0002

Describe in detail the Offeror's plan to prepare for and execute a clinical study described in the timeframe indicated. This plan should detail the activities that must be completed prior to study execution, activities required to maintain readiness capability and include a clear, executable process for initiating the study within the timeframe required. The Offeror shall submit a Gantt chart presented electronically as an integrated project plan in Microsoft Project 2007 format. The Gantt chart must contain sufficient detail to permit reviewers to make a realistic evaluation of the Offeror's likelihood of success. The Gantt chart should contain and track to a Work Breakdown Structure (WBS). The Gantt chart should show successors and predecessors, and milestones. The Offeror shall submit an Integrated Project Plan that outlines key, critical path milestones, with "go/no go" decision criteria (entrance and exit criteria for each phase of the project). The project plan should include, but not be limited to, milestones in manufacturing, regulatory submissions, and storage and delivery of product.

The business portion of the Offeror's response to Sample Request for Task Order Response 0002 shall be limited to 15 pages and shall be included in the Offeror's business proposal as described in SECTION L.3.

L.2.2. Appendices to Technical Proposal

A **Risk Mitigation Plan** to address potential problems that may arise and remediation plans to circumvent major time disruption to the project. Each of these documents can be revised during negotiations with the successful Offeror and will be incorporated into the contract. The risk mitigation will be finalized 90 days after contract award.

The Offeror shall describe their **Security Plan**, which covers physical, personnel, transport mechanisms and staffing, and Information Technology (IT) infrastructure security.

The Offeror shall provide the **contact information** of their U.S. Government partners in the conduct of any research or other work that will be completed at a U.S. Government facility or using U.S. Government personnel during the course of the contract. The Offeror shall indicate whether the listed U.S. Government partners have been notified of the Offeror's intentions to respond to this RFP.

The Offeror shall provide **resumes of all Key Personnel. Resumes shall be limited to a maximum of two pages each.**

L.3. BUSINESS PROPOSAL

L.3.1. Forms

All forms must be executed as necessary in the indicated places by an official authorized to bind the Offeror.

The following forms shall be duly completed and submitted as a part of the Business Proposal:

1) Offeror's Points of Contact (Attachment 6)
2) Completed Disclosure of Lobbying Activities (Attachment 3)
3) A completed Representations and Certifications contained in Part IV, SECTION K, of this solicitation

L.3.2. Business Proposal Instructions

The business proposal shall not exceed 50 pages, and shall reflect all cost information per objective as delineated in the SOO.

The business proposal shall include the business portion of the Offeror's response to Sample Request for Task Order Response 0001 and Sample Request for Task Order Response 0002. The sample ROTR business proposals shall not exceed 15 pages each.

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(1) Type of Contract and Number of Award(s)

The Government intends to award one or more indefinite-delivery, indefinite-quantity (IDIQ) contract(s) for clinical study services. During the period of performance of the contract, the government may order, and the Contractor shall provide, services as identified in future Task Orders. At the discretion of the government, Task Orders issued under this contract may be Firm-Fixed Price (FFP) or Cost Reimbursement (CR).

(2) Commitment of Public Funds

The contracting officer is the only individual who can legally commit the Government to the expenditure of public funds in connection with the proposed procurement. Any other commitment, either explicit or implied, is invalid.

(3) Communications Prior to Contract Award

Offerors shall direct all communications to the attention of the contract Specialist or contracting Officer cited on the face page of this RFP. Communications with any other Government official regarding this RFP is strictly prohibited, and may disqualify your proposal for further consideration.

(4) Late Proposals and Revisions

HHSAR 352.215-70 (Jan 2006) is applicable to this solicitation.

(5) Alternate Proposals

The Offeror may, at its discretion, submit alternate proposals or proposals that deviate from this solicitation's requirements; provided that the Offeror also submits a proposal for performance of the work, as specified in the SOO. Alternate proposals may be considered if performance would be improved or not compromised, and if they are in the best interest of the Government. Alternate proposals, or deviations from any requirements of this RFP, must be clearly identified.

(6) Past performance information

Offerors shall submit the following information as part of their business proposal for both the Offeror and proposed major subcontractors.

The Offeror shall provide a list of the last five (5) contracts completed during the past three years and all contracts currently in process. Contracts listed may include those entered into by the Federal Government, agencies of state and local governments and commercial customers. Offerors that are newly formed entities without prior contracts should list contracts and subcontracts as required above for all key personnel.

(a) Name of Contracting Organization
(b) Contract Number
(c) Total Contract Value
(d) Description of Requirement
(e) Contracting Officer's name and telephone number
(f) Program Manager's name and telephone number

L.3.3. Small Business Subcontracting Plan

If the proposed contract exceeds a total estimated cost of $650,000 for the entire period of performance, the Offeror shall be required to submit an acceptable subcontracting plan in accordance with the terms of the clause entitled "Small Business Subcontracting Plan," FAR Clause No. 52.219-9, incorporated herein by reference in this Request for Proposals:

(a) THIS PROVISION DOES NOT APPLY TO SMALL BUSINESS CONCERNS.

(b) The term "subcontract" means any agreement (other than one involving an employer-employee relationship) entered into by a Federal Government prime Contractor or subcontractor calling for supplies or services required for the performance of the original contract or subcontract. This includes, but is not limited to, agreements/purchase orders for supplies and services such as equipment purchase, copying services, and travel services.

(c) The Offeror understands that:

(1) No contract will be awarded unless and until an acceptable plan is negotiated with the Contracting Officer which plan will be incorporated into the contract, as a material part thereof.

(2) An acceptable plan must, in the determination of the Contracting Officer, provide the maximum practicable opportunity for Small Businesses, Small Disadvantaged Businesses, Women-Owned Small businesses, HUBZone Small Businesses, Veteran-Owned Small Businesses, and Service Disabled Veteran-Owned Small Businesses to participate in the performance of the contract.

(3) If a subcontracting plan acceptable to the Contracting Officer is not negotiated within the time limits prescribed by the contracting activity and such failure arises out of causes within the control and with the fault or negligence of the Offeror, the Offeror shall be ineligible for an award. The Contracting Officer shall notify the Contractor in writing of the reasons for determining a subcontracting plan unacceptable early enough in the negotiation process to allow the Contractor to modify the plan within the time limits prescribed.

(4) Prior compliance of the Offeror with other such subcontracting plans under previous contracts will be considered by the Contracting Officer in determining the responsibility of the Offeror for award of the contract.

(5) It is the Offeror's responsibility to develop a satisfactory subcontracting plan with respect to Small Business Concerns, Small Disadvantaged Business Concerns, Women-Owned Small Business Concerns, HUBZone Small Business Concerns, Veteran-Owned Small Business Concerns, and Service Disabled Veteran-Owned Small Business Concerns that each such aspect of the Offeror's plan will be judged independent of the other.

(6) The Offeror will submit, as required by the Contracting Officer, subcontracting reports in accordance with the instructions thereon, and as further directed by the Contracting Officer. Subcontractors will also submit these reports to the Government's Contracting Officer or as otherwise directed, with a copy to the prime Contractor's designated small and disadvantaged business liaison.

(d) Each plan must contain the following:

(1) Goals, expressed in terms of percentages of total planned subcontracting dollars, for the use of Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Business Concerns as subcontractors.

(2) A statement of total dollars planned to be subcontracted. A statement of total dollars to be subcontracted to each of the following type of small business concerns: Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses.

(3) A description of the principal types of supplies and services to be subcontracted with an identification of which supplies and services are expected to be subcontracted to Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned and/or Service Disabled Veteran-Owned Small Business Concerns.

(4) A description of the method used to develop the subcontracting goals.

(5) A description of the method used to identify potential sources for solicitation purposes.

(6) A statement as to whether or not indirect costs were included in establishing subcontracting goals. If they were, a description of the method used to determine the proportionate share of indirect costs to be incurred with Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses.

(7) The name of the individual employed by the Offeror who will administer the Offeror's subcontracting program and a description of his/her duties.

(8) A description of the efforts the Offeror will make to assure that Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses have an equitable chance to compete for subcontracts.

(9) Assurances that the Offeror will include in all subcontracts the contract clause "Utilization of Small Business Concerns." Assure that all subcontractors, other than small businesses, in excess of $650,000 adopt a plan similar to the plan agreed upon by the Offeror.

(10) Assurances that the Offeror (and any required subcontractors) will cooperate in studies or surveys as required and submit required reports (SF 294 and SF 295) to the Government.

(11) List the types of records the Offeror will maintain to demonstrate procedures that have been adopted to comply with the requirement and goals in the plan, including establishing source lists. Also, the Offeror shall describe its efforts to locate Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses and award subcontracts to them.

The anticipated minimum subcontracting goals for this solicitation are as follows:

- 33% for Small Business
- 5% for Small Disadvantaged Business
- 5% for Women-Owned Small Business
- 3% for HUBZone Small Business
- 3% for Veteran-Owned Small Business
- 3% for Service-Disabled Veteran-owned Small Business

A Subcontracting Plan must be submitted with the original proposal and will be subject to negotiations if your proposal is determined to be in the competitive range. Small Business Subcontracting Plan Format (must be submitted with your original Business Proposal) **http://www.hhs.gov/osdbu/forms.html**

Assistance with Obtaining Small Business Sources: If assistance is needed to locate small business sources, contact the Small Business Specialist (SBS) supporting the OPDIV. SBS contact information is located on the OSDBU website (http://www.hhs.gov/about/smallbusiness/osdbustaff.html) or you may contact the OSDBU headquarters at (202) 690-7300.

L.3.4. Other Administrative Data

(1) The proposal must stipulate that it is predicated upon all the terms and conditions of this RFP. In addition, it must contain a statement to the effect that it is firm for a period of at least 60 days from the date of receipt by the Government.

(2) The proposal must list any current commitments with the Government relating to the work or services and indicate whether these commitments will or will not interfere with the completion of work and services as contemplated under this proposal.

(3) The proposal must identify any former HHS employee(s) to be utilized on this project by providing the individual's name when employed by HHS, where employed, and the capacity in which employed.

(4) The Offeror must demonstrate that it has the necessary financial capacity, working capital, and other resources to perform the contract without assistance from any outside source. In addition to the submission of financial statements, this includes submission of information regarding available line of credit, bonding capability, and available plant and facilities for contract performance. (If assistance from outside sources is required, indicate the amount required and the anticipated source(s).)

(5) It is HHS policy that contractors provide all equipment and facilities necessary for performance of contracts; however, in some instances, an exception may be granted to provide Government furnished property or to authorize purchase with contract funds. If additional equipment must be acquired, you must include in your proposal a description and the estimated cost of each item, and state whether you propose to furnish the item with your own funds. The Offeror must identify all Government-owned property in its possession that it proposes to use in performing the prospective contract.

L.4. INQUIRIES

Inquiries concerning the solicitation document should be submitted in writing. Any additions, deletions, or changes to the solicitation will be made by an amendment.

OFFERORS ARE INSTRUCTED SPECIFICALLY TO CONTACT ONLY THE SOLICITATION CONTRACTING OFFICIALS (LISTED BELOW) IN CONNECTION WITH ANY ASPECT OF THIS REQUIREMENT PRIOR TO CONTRACT AWARD. PROPOSALS AND ALL CORRESPONDENCE RELATING TO THE SOLICITATION DOCUMENT SHALL BE SUBMITTED TO THE CONTRACTING OFFICIAL.

Inquiries should be received at the Contracting Office no later than TEN (10) business days prior to the proposal due date, and maybe submitted via e-mail to MCM-CSN@hhs.gov.

L.5. INCURRING COSTS

The costs of preparing responses to this solicitation are not considered an allowable direct charge on any resultant award. Proposal preparation costs will not be considered.

L.6. NAICS CODE AND SIZE STANDARD

The following information is to be used by the Offeror in preparing its Representations and Certifications (See SECTION K of this RFP), specifically in completing the FAR provision 52.219-1, Small Business Program Representation.

(1) The NAICS Code is 541711.
(2) The small business size standard is 500 employees.

L.7. THIS REQUIREMENT IS NOT SET-ASIDE FOR SMALL BUSINESS

This requirement is not set-aside for small business. However, the Federal Acquisition Regulation (FAR) requires in every solicitation, (except for foreign acquisitions) the inclusion of the North American Industry Classification System (NAICS) Code and corresponding size standard which best describes the nature of the requirement in the solicitation.

L.8. COMMITMENT OF PUBLIC FUNDS

The Contracting Officer is the only individual who can legally commit the Government to the expenditure of public funds in connection with the proposed procurement. Any other commitment, either explicit or implied, is invalid.

L.9. USE OF THE METRIC SYSTEM OF MEASUREMENT

It is the policy of the Department of Health and Human Services to support the Federal transition to the metric system and to use the metric system of measurement in all procurements, grants, and other business related activities unless such use is impracticable or is likely to cause significant inefficiencies. The Offeror is encouraged to prepare their proposal using either "Hard Metric," "Soft Metric," or "Dual Systems" of measurement. The following definitions are provided for your information:

Hard Metric - The replacement of a standard inch-pound size with an accepted metric size for a particular purpose. An example of size substitution might be: selling or packaging liquids by the liter instead of by the pint or quart (as for soft drinks), or instead of by the gallon (as for gasoline).

Soft Metric - The result of a mathematical conversion of inch-pound measurements to metric equivalents for a particular purpose. The physical characteristics are not changed.

Dual Systems - The use of both inch-pound and metric systems. For example, an item is designed, produced, and described in inch-pound values with soft metric values also shown for information or comparison purposes.

L.10. POTENTIAL AWARD WITHOUT DISCUSSIONS

The Government reserves the right to award a contract under this solicitation without discussions.

L.11. SOLICITATION PROVISIONS INCORPORATED BY REFERENCE

The following provisions are incorporated by reference in this solicitation:

FAR Clause 52.215-1, Instructions to Offerors – Competitive Acquisitions, Alternate I (Jan 2004).

FAR Clause 52.215-8, Order of Precedence-Uniform Contract Format, (October 1997).

FAR Clause 52.215-16, Facilities Capital Cost of Money, (Jun 2003).

FAR Clause 52.222-24, Pre-award On-Site Equal Opportunity Compliance Evaluation, (Over $10,000,000), (February 1999).

FAR Clause 52.225-25, Prohibition on Contracting with Entities Engaging in Sanctioned Activities Relating to Iran—Representation and Certification, (Dec 2012)

FAR 52.233-2, Service of Protest (Sep 2006)

(a) Protests, as defined in section 33.101 of the Federal Acquisition Regulation, that are filed directly with an agency, and copies of any protests that are filed with the General Accounting Office (GAO), shall be served on the Contracting Officer (addressed as follows) by obtaining written and dated acknowledgment of receipt from:

Contracting Officer
Department of Health & Human Services
Assistant Secretary for Preparedness & Response
Office of Acquisition Management, Contracts and Grants
330 Independence Avenue, S.W. Room G640
Washington, DC 20201

(b) The copy of any protest shall be received in the office designated above within one day of filing a protest with the GAO.

L.12. PRE-PROPOSAL CONFERENCE

A pre-proposal conference will be held with prospective Offerors in Washington, DC on April 24, 2013. The pre-proposal conference will be held for the purpose of providing information concerning the Government's requirements which may be helpful in the preparation of proposals and for answering any questions which potential Offerors may have regarding this solicitation.

HHS/ASPR will release an amendment to the RFP providing specific details regarding the date, time and exact location of the pre-proposal conference.

Because of space limitations, each prospective Offeror shall be limited to a total of two (2) representatives. If a prospective Offeror has a subcontractor, then the subcontractor shall be limited to one (1) representative.

The success of this type of conference depends largely on the lead-time available to the Government for research in connection with questions submitted by Offerors. Therefore, you are requested to submit your questions concerning any areas of uncertainty which, in your opinion, require clarification or correction, in sufficient time to be received by 5:00 P.M. local time April 17, 2013.

Your questions should be submitted to **MCM-CSN@hhs.gov**. The email subject line should read, "Pre-proposal conference, RFP No. RFP-13-100-SOL-00008" A set of all questions and answers will be furnished simultaneously to all prospective Offerors whether or not they are in attendance.

Attendance at the pre-proposal conference is recommended; however, attendance is not a prerequisite for proposal submission and will not be considered a factor in proposal evaluation.

L.13. EXTENT OF SMALL DISADVANTAGED BUSINESS PARTICIPATION

(Note. This paragraph on small disadvantaged business participation applies to all Offerors, including Offerors who are small business concerns even though they are exempt from the requirement for a Subcontracting Plan under FAR 52.219.)

In accordance with FAR Subpart 15.304(c)(4), the extent of participation of Small Disadvantaged Business (SDB) concerns in performance of the contract in the authorized NAICS Industry Subsectors shall be evaluated in unrestricted competitive acquisitions expected to exceed $650,000 ($1,500,000 for construction) subject to certain limitations (see FAR 19.201 and 19.1202). The dollar amounts cited above include any option years/option quantities that may be included in this solicitation. The definition of a "small disadvantaged business" is cited in FAR 19.001.

The factor entitled “Extent of Small Disadvantaged Business Participation” as set forth under the Evaluation Criteria in Section M shall be used for evaluation purposes.
The Department of Commerce determines, on an annual basis, by Subsectors, as contained in the North American Industry Classification System (NAICS) codes, and region, if any, the authorized SDB procurement mechanisms and applicable factors (percentages). The NAICS codes can be found at: http://www.sba.gov/size

The Department of Commerce website for the annual determination for NAICS codes* is:
http://www.arnet.gov/References/sdbadjustments.htm

*Note: Public Law 103-355, which authorized the SDB Price Evaluation Adjustment (PEA) and associated percentages/factors expired on December 9, 2004, therefore, the percentages shown at this website are no longer applicable.

Offerors shall include with their offers, SDB targets, expressed as dollars and percentages of total contract value, in each of the applicable, authorized NAICS Industry Subsector(s). The applicable authorized NAICS Industry Subsector(s) for this project is (are) identified elsewhere in this RFP. A total target for SDB participation by the prime contractor, that includes any joint ventures and team members, shall be provided as well as a total target for SDB participation by subcontractors. In addition, Offerors must provide information that describes their plans for meeting the targets set forth in their proposal. This information shall be provided in one clearly marked section of the Business Proposal, which shall describe the extent of participation of SDB concerns in the performance of the contract.

If the evaluation factor in this solicitation includes an SDB evaluation factor or subfactor that considers the extent to which SDB concerns are specifically identified, the SDB concerns considered in the evaluation shall be listed in any resultant contract. Offerors should note that addressing the extent of small disadvantaged business participation is not in any way intended to be a substitute for submission of the subcontracting plan, if it is required by this solicitation. An example of the type of information that might be given (in addition to the narrative describing the plan for meeting the targets) follows:

EXAMPLE

Targets for SDB Participation - NAICS Industry Subsector 223

	SDB Percentage of Total Contract Value
Total Contract Value- $1,000,000	5%
SDB Participation by Prime	2%
(Includes joint venture partners and team arrangements)*	
SDB Participation by subcontractors	3%

*Note: FAR Subpart 9.6 defines "Contractor team arrangements" to include two or more companies forming a partnership or joint venture to act as a potential prime contractor, or a potential prime contractor who agrees with one or more companies to have them act as its subcontractors on a specific contract or acquisition program. For purposes of evaluation of the SDB participation factor, FAR 19.1202-4 requires that SDB joint ventures and teaming arrangements at the prime level be presented separately from SDB participation by subcontractors.

SECTION M – EVALUATION FACTORS FOR AWARD

M.1. TECHNICAL EVALUATION

M.1.1. Basis of Award

Selection of an Offeror for contract award will be based on an evaluation of proposals against the Evaluation Factors defined in this SECTION M. The non-cost factors in descending order of importance are: Mandatory criteria, Technical Evaluation Criteria, Past Performance, and Small Disadvantaged Business (SDB) participation. Offerors are advised that in the evaluation process, all evaluation factors other than cost or price, when combined, are significantly more important than cost or price. Technical activities must connect directly to costs in the business proposal. The trade off process described in FAR 15.101-1 may be employed. This process permits tradeoffs among cost/price and non-cost factors and allows the Government to consider award(s) to other than the lowest priced or highest technically rated Offeror. In any case, the Government reserves the right to make an award(s) to that Offeror whose proposal provides the best overall value to the Government.

In the case of multiple awards, the Government will make their determination of best overall value to the Government by considering, as a part of its award determination, different technological capabilities that best satisfies the Government's overarching technological capability needs.

The evaluation will be based on the demonstrated capabilities of the prospective Contractors in relation to the needs of the project as set forth in the RFP. The merits and confidence ratings of each proposal will be evaluated carefully. Each proposal must document the feasibility of successful implementation of the requirements of the RFP. Each Offeror must submit a proposal that separately and sufficiently addresses each of the evaluation criteria specified below as they relate to the Statement of Objectives.

The Contracting Officer intends to evaluate proposals and make an award without discussions. However, the Government reserves the right to conduct discussions if it is determined to be in the best interest of the Government. Therefore, Offerors are encouraged to ensure that initial proposals contain the Offeror's most favorable terms and reflect its best possible performance potential.

M.1.2. Mandatory Criteria for Eligibility

Offerors shall have completed at least one infectious disease or chemical, biological, radiological or nuclear clinical study under a FDA Investigational New Drug (IND) application in the last 5 years.

The mandatory criteria for eligibility must be met at the time of proposal submission. Offeror proposals that do not meet the mandatory criteria for eligibility will not be eligible for further evaluation.

M.1.3. Technical Evaluation Criteria

Proposals meeting the Mandatory Criteria for Eligibility shall be evaluated against the following evaluation factors listed in order of importance to the U.S. Government. ***Offerors must address each evaluation factor and each subfactor to be considered for award:***

(1) Technical Plan/Approach
(2) Organizational Experience and Competency
(3) Personnel Qualifications
(4) Program and Risk Management Plan
(5) Sample Request for Task Order Response 0001
(6) Sample Request for Task Order Response 0002

M.1.3.1. Technical Plan/Approach

The Offeror will be evaluated on the appropriateness and adequacy of the proposed plans, organizational experience, procedures, personnel education and availability and understanding of the problems and deficiencies of providing a broad range of clinical services for biomedical[1] products.

Subfactors a, b, c and d below are of equal importance and are greater than items e, f, g and h below, which are also of importance:

a. Safety monitoring

b. Clinical trial execution

c. Quality metrics

d. Clinical site management

e. Planning and pre-study activities

f. Document creation and management

g. Identification and contractual agreements with clinical research vendors to support studies, as needed

h. Data management and Biostatistics

M.1.3.2. Organizational Experience and Competency

Offerors will be able to complete the majority of tasks associated with the completion of a Phase 1-4 trials with internal resources. Explicit identification of internal/external resources is required. Teaming and subcontracting arrangements are permitted. The Offeror will be evaluated on experience and competency for the following subfactors that are of equal importance. Explicit identification of internal/external resources is required.

a. Project Management: Offerors will be evaluated for their experience and competency in managing the costs of trials, up-front contingency planning, risk management, Earned Value management, Metrics for meeting timelines, Management structure of the Contractor

[1] Biomedical as used is inclusive of products regulated by CBER, CDER and CDRH.

and proposed subcontractors, network of clinical sites or investigators, CRA quality metrics, change order metrics, financial strength/stability, global footprint, and local regulatory knowledge.

b. Relevant Experience: Offerors will be evaluated on successfully completed Phase 1,2,3 or 4 clinical studies over the last 5 years, Offeror's utilization of innovative solutions to problems arising in clinical studies, and ability to maintain a Phase I unit. Offerors will be evaluated for their experience and competency in conducting studies in special populations including pediatric, elderly, hepatic insufficiency, renal impairment and immunocompromised.
c. Data management: Past performance of Offerors will be evaluated on the effectiveness of data quality assurance plans, use of standard data update and control, quality metrics, technology for real-time access to data, database uptime statistics, SOPs and metrics on time from last subject last visit to database lock and database lock to draft clinical study report.
d. Quality management: Offerors should provide relevant experience metrics for quality management.
e. International study capabilities: International study capabilities including northern and southern hemisphere clinical sites will be evaluated.
f. Engagement with USG safety monitoring efforts: Offerors should describe their level of engagement with existing USG safety monitoring efforts including but not limited to the Vaccine Adverse Event Reporting System (VAERS) and the Vaccines and Medications in Pregnancy Surveillance System (VAMPSS).
g. Emergency response capabilities: Offerors should describe their strategy or plan for preparing to conduct clinical studies during a declared public health emergency.

M.1.3.3. Personnel Qualifications

The key personnel will be evaluated by the USG for individual training and contributions in previous clinical programs relevant to this statement of objectives. These include, but are not limited to experts in, clinical operations, quality management, data management, statistical support, medical expertise, pharmacovigilance, laboratory science, and regulatory science. In addition, the Contractor leadership will be evaluated on successful efforts of a similar magnitude and scope of this statement of objectives. Staff continuity and or staff turnover metrics shall be presented for evaluation. Key personnel shall be identified. As appropriate, key personnel for Objectives 1 and 2 should be identified.

M.1.3.4. Program and Risk Management Plan

The Offeror will be evaluated on the overall sufficiency of the comprehensive program management plan.

The plan will be evaluated on the risk management component highlighting potential problems and/or issues that may arise during the life of the contract, their impact on cost, performance and timelines, and the appropriate plans to mitigate these risks.

Adequacy of the plan to identify and remediate problems in subcontractor performance and in risk mitigation inherent during the conduct of clinical trials.

Suitability of the plan for how the Offeror will communicate with the COR and the CO, as well as establish lines of communication between all performance sites and activities.

Suitability of the plan for soliciting, evaluating, negotiating, awarding and managing any proposed subcontracts in accordance with Federal regulations.

M.1.3.5. Sample Request for Task Order Response 0001

Note: The Sample ROTRs are included for evaluation purposes only. No Task Order award will result from Offerors' Sample ROTR responses.

The evaluation subfactors for Sample RTOR 0001 are Technical Approach, Quality Assurance/Quality Control Plan, and Experience of Key Personnel. For evaluation purposes, the Technical Approach is the most important factor and is significantly more important than the Quality Assurance/Quality Control Plan. When combined the Technical Approach and Quality Assurance/Quality Control Plan are more important than price. Cross-reference to the main volume of the technical proposal is encouraged to limit the amount of redundant information.

The response to this evaluation element should include a fully detailed technical and business proposal. The business portion of the Offeror's response to Sample RTOR 0001 must be included in the Offeror's Business Proposal.

a. Technical Approach. The respondent must demonstrate the capability to provide a technical approach as required by the RTOR. The technical approach response shall contain sufficient quantitative details (without reference to cost or price) to permit a complete and accurate evaluation of the approach from strictly a technical viewpoint.

b. Quality Assurance/Quality Control Plan. The respondent must demonstrate the capability to provide management quality systems plan as required by the SOW.

c. Experience of Key Personnel. The respondent must demonstrate background and experience of key personnel relevant to the technical requirements of the SOW.

M.1.3.6. Sample Request for Task Order Response 0002

Note: The Sample ROTRs are included for evaluation purposes only. No Task Order award will result from Offerors' Sample ROTR responses.

The evaluation subfactors for Sample RTOR 0002 are Technical Approach, Quality Assurance/Quality Control Plan, and Experience of Key Personnel. For evaluation purposes, the Technical Approach is the most important factor and is significantly more important than the Quality Assurance/Quality Control Plan. When combined the Technical Approach and Quality Assurance/Quality Control Plan are more important than price. Cross-reference to the main volume of the technical proposal is encouraged to limit the amount of redundant information.

a. Technical Approach. The respondent must demonstrate the capability to provide a technical approach as required by the RTOR. The technical approach response shall contain sufficient quantitative details (without reference to cost or price) to permit a complete and accurate evaluation of the approach from strictly a technical viewpoint.

b. Quality Assurance/Quality Control Plan. The respondent must demonstrate the capability to provide management quality systems plan as required by the SOW.

c. Experience of Key Personnel. The respondent must demonstrate background and experience of key personnel relevant to the technical requirements of the SOW.

M.1.4. Merit and Confidence Ratings

Evaluators will assign both a merit and a confidence rating to the sub-factors of six evaluation factors noted in items (1) through (6) above. One merit and one confidence rating will be assigned to each Technical Evaluation Factor. The ratings for merit and confidence will be considered of equal importance. The ratings assigned to the sub-factors will be consolidated by the evaluators into a single, overall rating per factor.

M.1.4.1. Merit Ratings

The following color-code/adjectival ratings will be used in rating the merit portion of all of the sub-factors:

- Outstanding: Greatly exceeds the minimum performance or capability requirements in a beneficial way to the USG. There are no weaknesses or deficiencies. Those aspects of a factor resulting in an outstanding rating may be incorporated into the resulting contract.
- Excellent: Exceeds the minimum performance or capability requirements in a beneficial way to the USG. There are no significant weaknesses. Those aspects of a factor resulting in an excellent rating may be incorporated into the resulting contract.
- Acceptable: Meets the minimum performance or capability requirements. There may be minor but correctable weaknesses.
- Marginal: May meet the performance or capability requirements. There are apparent or moderate weaknesses that are correctable. An overall merit rating of Marginal is not eligible for award.
- Unacceptable: Fails to meet the performance or capability requirements. There are unacceptable weaknesses. An overall merit rating of Unacceptable is not eligible for award.

M.1.4.2. Confidence Ratings

The following color-code/adjectival ratings will be used in rating the confidence portion of all of the sub-factors:

- High Confidence: Evaluated that no doubt exists that the Offeror will successfully perform the proposed effort. The Offeror's understanding of the project, and soundness of approach are such that virtually no USG intervention is expected to be required in achieving the proposed level of performance.
- Significant Confidence: Evaluated with a certainty that the Offeror will successfully perform the proposed approach with minor potential cause for disruption of schedule, increased cost or degradation of performance. The Offeror's understanding of the project, and soundness of approach are such that little USG intervention is expected to be required in achieving the proposed level of performance.
- Confidence: Offeror can successfully perform the proposed approach with little potential cause for disruption of schedule, increased cost or degradation of performance. The

Offeror's understanding of the project, and soundness of approach are such that moderate USG intervention is expected to be required in achieving the proposed level of performance.

- Little Confidence: Substantial doubt exists that the Offeror can successfully perform the proposed approach with little potential cause for disruption of schedule, increased cost or degradation of performance. The Offeror's understanding of the project, and soundness of approach are such that substantial USG intervention is expected to be required in achieving the proposed level of performance. An overall rating of Little Confidence is not eligible for award.

- No Confidence: Extreme doubt exists that the Offeror can successfully perform the proposed approach with little potential cause for disruption of schedule, increased cost or degradation of performance. Regardless of the degree of USG intervention or oversight, successful performance is doubtful. An overall rating of No Confidence is not eligible for award.

M.2. Business Proposal Evaluation

Business proposals will be evaluated to determine responsible and responsive Offerors who provide the best value to the Government.

M.2.1. Base Contract Business Proposal Evaluation

The Offeror's business proposal and proposed cost/pricing shall be evaluated separately and then the overall analysis of the business proposal will be evaluated to reach the best overall value to the Government. The proposed cost/prices will be evaluated to determine cost realism and reasonableness. The basis of evaluation may include the use of various cost/price realism analysis techniques to ensure a fair and reasonable price such as, but not limited to:

- Comparison of proposed prices received in response to the solicitation.
- Comparison of proposed prices with resources proposed.
- Obtaining information/reports from Government agencies, and the Independent Government Cost Estimate.
- Review and analysis of cost and pricing data as well as other cost and pricing data submitted.

M.2.2. Sample ROTR 0001 Business Proposal Evaluation

To be viable for award, respondent's price must be determined reasonable. The respondent's price submission shall represent the respondent's best efforts to respond to Sample RTOR 0001. Any inconsistency between promised performance and price shall be explained in the submission. For example, if unique, innovative approaches are the basis for an unusually low price, the nature of these approaches and their impact on price shall be explained. If a respondent proposes to absorb a portion of price, the respondent must also explain the impact on the estimated price. Any significant inconsistency, left unexplained, may raise a fundamental question of the respondent's understanding of the nature and scope of the work required in the task order, and of the respondent's ability to perform the tasks within the fiscal constraints thereof, and may be cause for rejection of the

submission. The techniques and procedures described under FAR Part 15.404 will be the primary means of assessing price submission reasonableness.

M.2.3. Sample ROTR 0002 Business Proposal Evaluation

To be viable for award, respondent's price must be determined reasonable. The respondent's price submission shall represent the respondent's best efforts to respond to Sample RTOR 0002. Any inconsistency between promised performance and price shall be explained in the submission. For example, if unique, innovative approaches are the basis for an unusually low price, the nature of these approaches and their impact on price shall be explained. If a respondent proposes to absorb a portion of price, the respondent must also explain the impact on the estimated price. Any significant inconsistency, left unexplained, may raise a fundamental question of the respondent's understanding of the nature and scope of the work required in the task order, and of the respondent's ability to perform the tasks within the fiscal constraints thereof, and may be cause for rejection of the submission. The techniques and procedures described under FAR Part 15.404 will be the primary means of assessing price submission reasonableness.

M.2.4. Past Performance Evaluation

Each Offeror will be evaluated on their performance under existing and prior contracts for similar products or services. Performance information will be used for both responsibility determinations, and as an evaluation factor against which the Offerors' relative rankings will be compared to assure the best value to the Government. The Government will focus on information that demonstrates quality of performance, relative to the size and complexity of the acquisition under consideration. The government is not required to contact all references provided by the Offeror, and references other than those identified by the Offeror, may be contacted by the Government to obtain additional information that will be used in the evaluation of the Offeror's past performance. The lack of a relevant performance record may result in an unknown performance risk assessment, which will neither be used to the advantage nor disadvantage of the Offeror. In this case, past performance will be noted as "No relevant past-performance history identifiable."

The following rating method shall be used in the evaluation of past performance information:

- Acceptable – Based on the Offeror's performance record little to no doubt exists that the Offeror will successfully perform the required effort. Sources of information indicate that the Offeror's performance is at least average or that favorable reports are offset by unfavorable reports.

- Unacceptable – Based on the Offeror's performance record some to serious doubt exist that the Offer will successfully perform the required effort. Sources of information made unfavorable to unsatisfactory reports about the Offeror's performance and they express concern about doing business with the Offeror again or would not do business with the Offeror again.

- Neutral – The lack of a relevant performance record, or the unavailability of past performance information, may result in an undetermined past performance assessment, which will neither be used to the advantage nor disadvantage of the Offeror.

The Government reserves the right to consider past performance information from any source.

M.2.5. Extent of Small Disadvantaged Business (SDB) Participation

SDB participation will not be scored, but the Government's conclusions about overall commitment and realism of the Offeror's SDB Participation targets will be used in determining the relative merits of the Offeror's proposal and in selecting the Offeror whose proposal is considered to offer the best value to the Government.

The extent of the Offeror's Small Disadvantaged Business Participation Targets will be evaluated before determination of the competitive range. Evaluation of SDB participation will be assessed based on consideration of the information presented in the Offeror's proposal. The Government is seeking to determine whether the Offeror has demonstrated a commitment to use SDB concerns for the work that it intends to perform.

Offers will be evaluated on the following sub-factors:

a. Extent to which SDB concerns are specifically identified
b. Extent of commitment to use SDB concerns
c. Complexity and variety of the work SDB concerns are to perform
d. Realism of the proposal
e. Past performance of Offerors in complying with subcontracting plan goals for SDB concerns and monetary targets for SDB participation
f. Extent of participation of SDB concerns in terms of the value of the total acquisition.

M.3. Evaluation of Options

It is anticipated that any resultant contract from this solicitation will contain option provision(s).

FAR 52.217-5, Evaluation of Options (July 1990)

Except when it is determined in accordance with FAR 17.206(b) not to be in the Government's best interests, the Government will evaluate offers for award purposes by adding the total price for all options to the total price for the basic requirement. Evaluation of options will not obligate the Government to exercise the option(s).

(End of provision)

ATTACHMENT #1

SAMPLE REQUEST FOR TASK ORDER RESPONSE 0001

Note: The Sample ROTRs are included for evaluation purposes only. No Task Order award will result from Offerors' Sample ROTR responses.

Date of Issue: **TBD**

Description of Services: Randomized, Phase 2, Placebo-Controlled Study of the Safety, Reactogenicity, and Immunogenicity of Intramuscular Inactivated Influenza A/H5N1 Vaccine Given with Adjuvant in Healthy Adults

Closing Date/Time: **TBD**

Dear Contractors:

This is a Request for Task Order Response (RTOR) for services to be provided under the Biomedical Advanced Research and Development Authority (BARDA) Medical Countermeasures Clinical Studies Network (MCM CSN) IDIQ contract vehicle. There is no incumbent contractor. Fair opportunity is herein provided to all BARDA MCM CSN prime contractors.

Attached are all related documents for this RTOR. Please ensure that you have read the attached documents, including specific response submission instructions that are included in this RTOR, and submit your response electronically by the date and time indicated above.

MCM CSN partners choosing not to submit a proposal shall provide an explanation of their decision to not submit a proposal no later than seven (7) business days after receipt of this official RTOR.

All replies should be directed via e-mail to {INSERT TOCO/TOCS NAME} and {INSERT BACKUP TOCO/TOCS NAME}. All items within the RTOR must be completed and returned by closing due date and time.

In addition to this letter, this RTOR includes the following exhibits:

Attachments

- ☒ Attachment 1A – Additional Terms and Conditions
- ☐ Attachment 1B – Pricing Schedule/CLIN Structure
- ☒ Attachment 1C – Statement of Work and/or Statement of Objectives
- ☐ Attachment 1D – Risk Register
- ☒ Attachment 1E – Submission Instructions/ Evaluation Criteria
  - ☒ 5 A – Instructions
  - ☒ 5 B – Evaluation Criteria
  - ☒ 5 C – Basis for Award
- ☐ Attachment 1F – Task Order Administration Information
- ☐ Attachment 1G – Past Performance Evaluation Form

Contract Type
The Government contemplates award of the following contract type:

☐ Cost Reimbursement ☒ Firm Fixed Price ☐ Mixed Cost Reimbursement/Firm Fixed Price

Anticipated Period of Performance
26 months from date of task order award.

Location of Performance
Contractor provided facilities.

Additional Instructions
The task order contracting officer (TOCO) reserves the right to withdraw and cancel this RTOR. In such an event, contractors shall be notified in writing of the TOCO's decision. This decision is final, conclusive and shall not be subject to the "Disputes" clause or the "Contract Disputes Act."

Your response must be in full compliance with the instructions in this RTOR and your basic contract. The response (to include price) shall be valid for sixty (60) calendar days. If you have any questions, please contact *{INSERT TOCO/TOCS NAME}* via email at *{INSERT TOCO/TOCS E-MAIL}* and copy *{INSERT BACKUP TOCO/TOCS NAME}* via email at *{INSERT BACKUP TOCO/TOCS E-MAIL}*

{INSERT TOCO NAME}

Task Order Contracting Officer

BARDA MCM CSN Request for Task Order Response (RTOR)

[Insert Date]

Notice to All MCM CSN Contractors:

This Request for Task Order Response is being issued to invite proposals for a Phase 2 study for stockpiled H5N1 influenza vaccine combined with adjuvant. This Phase 2 study will be conducted at sites in the United States starting in **January 2014**. This RTOR provides key timelines, parameters and assumptions for the conduct of the Phase 2 study. The protocol design is subject to further discussions with the FDA and may be amended. Respondents are requested to provide an initial proposal and cost estimates based upon the enclosed information. The budget proposal should be prepared and submitted to show the tasks outlined in Table 1, Attachment 2 and Attachment 3. Add additional or supplementary information to clarify any assumptions that you have used and to describe the processes and procedures that you would use. Please provide your budgets in the format in Attachment 2. Please include any suggestions you may have in conducting this study based on prior experience with vaccine studies. If you plan to use a subcontractor for any tasks, please specify the vendor or describe the process for vendor selection.

Along with the proposal, please provide a organizational chart of the proposed project team including CVs for your proposed program director, project manager, medical monitor, data management project manager, biostatistician, and other key members of your proposed team for those studies planned to start in **1Q2014**. Define the full time equivalent (FTE) commitment that each key team member will provide to BARDA for this project.

Protocol Synopsis

Title: Randomized, Phase 2, Placebo-Controlled Study of the Safety, Reactogenicity, and Immunogenicity of Intramuscular Inactivated Influenza A/H5N1 Vaccine Given with Adjuvant in Healthy Adults

Study Design

Approximately 400 healthy adults, 18 to 64 of age inclusive, will be enrolled into this randomized, placebo-controlled clinical trial. Subjects who meet the entry criteria for the study will be randomized 3:1 to receive two doses of intramuscular influenza A/H5N1 vaccine at 3.75 µg with adjuvant or placebo separated by 21 days. Subjects will be screened for health status by history, concomitant medications, vital signs (oral temperature, pulse and blood pressure) and complete physical examination (without genital and rectal exam) to include supraclavicular and axillary lymph node assessment within 21days prior to the first vaccination or on the day of, but prior to, first vaccination. Subjects must have an erythrocyte sedimentation rate (ESR) performed on a venous blood sample collected at screening (within 21 days prior to the first vaccination) or on the day of, but prior to, first vaccination, and the value must be confirmed as less than 30 mm per hour prior to randomization and first vaccination. All female subjects of childbearing potential must have a negative urine or serum pregnancy test within 24 hours prior to receipt of each vaccination.

Table 1: Study Description

STUDY PARAMETERS

Number of subjects	400
Number of sites	6
Target first subject first visit	January 2014
Enrollment duration	2 weeks
Target last subject last visit	February 2015
Study close out, data clean up, analysis and report preparation	8 weeks
Total program duration	24 months
Number of unique CRF pages	15
Number of CRF pages per subject	55
Central randomization/IVRS	Yes
Central laboratory	Yes
Total number of SAE expected	25
Final analysis Number of tables Number of listings Number of figures	 15 10 5

The following pertinent facts regarding this request for proposal:

Contract Type(s): **Firm Fixed Price**

Contract Duration: **26 months**

Security Requirements: None

Contractual History

There is no incumbent contractor. Materials will be obtained from two different manufacturers and data distribution agreements are required.

Site Visit

Site visits by HHS personnel are required post-award. See "Table 1: Scope of work and costs for each study activity" in Attachment 2 for details.

Pre-Proposal Conference

A pre-proposal conference is not anticipated.

Questions on Request for Task Order Response (RTOR)

If you have any questions, e-mail the TOCO at [insert name/e-mail] by [Insert date/time]. Questions submitted after this date will not be responded to.

Proposal Submittal Instructions

Due Date: [Insert Time and Time Zone, Date].

Submit to: [Insert contact information, e.g. CO name, e-mail or mailing address, FAX number…] via email at [TO-CO Email address]

Instructions to Offerors

General: This acquisition is being conducted under FAR 16.505; therefore, the contracting techniques under FAR part 15.3 do not apply. As such, the government is not obligated to determine a competitive range, conduct discussions with all contractors, or solicit final revised proposals. Offerors will be required to provide a cost/price and technical proposal in accordance with the instructions herein.

Cost/Price Proposal: Contractors are required to provide a cost/price proposal. Cost/price proposal must include a completed Attachment 2. Proposals should address the Offeror's technical approach, skill mix and hours, hourly rates, estimated travel, Other Direct Costs (ODCs), and total price.

The cost proposal should be sufficiently detailed to allow comprehensive understanding of cost reasonableness and realism. Supporting information for each cost element should be provided, including, but not limited to, Direct Labor, Fringe Benefits, Overhead, General and Administrative (G&A) expenses, Facilities Capital Cost of Money, Other Direct Costs and Profit consistent with your cost accounting system, provisional billing rates, and forward pricing rate agreements.

Technical Proposal

Fonts should not exceed 14 pts, and be no smaller than 11 points. Page margins should be no smaller than 1 inch. Pages should be 8.5" x 11". The technical proposal shall not exceed 20 pages in length. The business proposal should not exceed 15 pages in length. Gantt charts should be provided in native Microsoft project (or equivalent) format.

Your technical proposal should include the following:

Part A: Technical Approach

Technical approach to achieving the objectives of this RTOR.

Roles and responsibilities matrixes or clearly define roles in Part B: Experience of Key Personnel.

Contract Work Breakdown Structure.

Gantt chart including at a minimum the major tasks and critical subtasks.

Part B: Experience of Key Personnel

Provide Resumes of Key Personnel (include skills, required certifications if required by contract; relate resume experience to the required functional areas of the project.)

Part C: Past Performance

Identify recent relevant contracts.

Highlight any unique aspects of your proposal and explain how it is of benefit to the government and why your proposal represents the best value to the government.

Conflict of Interest

Any contractor (or member of its team and /or subcontractor) having a conflict of interest as defined under FAR Part 9.5 must identify the conflict as soon as it is known and provide a recommended mitigation plan. Mitigation plans are required whenever a competing contractor has had unequal access

to non-public information regarding the Task Order requirement, or has assisted the Government in defining the Task Order requirements or evaluation criteria.

Attachment 1A – Additional Terms and Conditions

The following provision is added to this RTOR:

Contractor's additional information

The contractor shall provide all personnel, management, supervision, equipment, tools, supplies, materials, transportation, and any other items and services necessary to perform the functions of the Statement of Work (SOW). The place of performance is: the contractor's facilities.

Inspection and Acceptance Inspection and acceptance of all work, performance, reports and other deliverables under this task order will be performed at the location specified in this RTOR by the Technical Monitor (TM). TMs are responsible for inspection of services under the Task Order (TO). The Government will record all surveillance observations. When an observation indicates defective performance, the TM will request the contractor's representative to initial the observation.

Deliveries or Performance **Twenty-six (26)** months from date of TO award, however, achievable schedules to complete the project earlier than this are encouraged.

Task Order Administrative Data.

Task Order Contracting Officer (TOCO) The Acquisitions Management Contracts and Grants Office (AMCG) is responsible for awarding this TO. The TOCO is {INSERT TOCO NAME}, {INSERT TOCO PHONE NUMBER}, {INSERT TOCO E-MAIL ADDRESS}.

TOCO Points of Contact The TOCO will be responsible for the administration of this TO and, alone, is authorized to take actions on behalf of the Government that result in changes in the terms and conditions of the TO. TOCO is {INSERT TOCO NAME}, {INSERT TOCO PHONE NUMBER},{INSERT TOCO E-MAIL ADDRESS}.

Technical Monitor (TM)

The Task Order Contracting Officer (TOCO) will designate a representative called the Technical Monitor (TM). The TM will be designated in writing to act as the TOCO representative in monitoring specified aspects of contractor performance, and a copy of the designation will be furnished to the Contractor. These aspects may include ensuring that the contractor's performance meets the standards set forth in the Task Order (TO), ensuring the contractor meets the technical requirements under the TO by the delivery date(s) and/or within the period of performance, and ensuring that the contractor performs within the price or estimated cost stated in the TO. The Contractor is cautioned to read the designation because certain authority under the TO is reserved solely for the TOCO. The term "Task Order Contracting Officer (TOCO)" as used throughout the TO shall be interpreted to include the designated Technical Monitor (TM) acting within the limits of their delegation of authority.

The TM will act in a liaison capacity to coordinate activities between the Contractor and the Government as required in the performance of the work under this TO.

No oral statements of any person whosoever will in any manner or degree modifies or otherwise affects the terms of this TO. The TOCO is the only person authorized to approve changes in any of the requirements under this TO, and notwithstanding any provisions contained elsewhere in this TO, the said authority remains solely with the Task Order Contracting Officer.

The TM will receive, review, approve, sign and submit the invoice to the TOCO to initiate contractor payment. Additional information will be provided in the awarded TO.

Prompt Payment Act: The due date for making an invoice payment is as follows: The 30th day after the designated billing office receives a proper invoice from the contractor.

Special Task Order Requirements. For example: “The Offeror shall propose a technical approach including a statement of work (SOW) that will achieve objectives 1 and 2 from the statement of objectives (SOO). Additional objectives are present in the SOO, but are for reference only at this time. Objectives 1 and 2 should be satisfied such that the products would ultimately be useful for satisfying other objectives, but no work on these other objectives is to be proposed in response to this request.”

All applicable contract clauses from the main IDIQ contract flow down to this MCM CSN Task Order.

Attachment 1B – Pricing Schedule/CLIN Structure

Table 1. Cost and Price Schedule:

Activities	BARDA	CRO	Direct Labor	Fringe Rate	Material Costs	Other Direct Costs	Other Indirect Costs	Pass through Costs	Total
1. Study and Protocol Planning									
Clinical Protocol and ICF template		X							
Site Procedures Manual Preparation and distribution to sites		X							
Investigator Brochure preparation	X								
Investigator Brochure distribution to sites		X							
Study Protocol and Planning Sub Total:									
2. Regulatory activities									
Preparation and collection of investigator regulatory document packages		X							
Trial Master File Preparation and Maintenance		X							
Regulatory activities Sub-Total									
3. Site Initiation									
Site identification and screening		X							
Pre-study site qualifications visits		X							
Site selection		X							
Investigator contract template development, distribution, budget negotiation, and contract establishment with sites		X							
Investigator meeting planning, attendance and conduct. Include pass through costs for meeting		X							

Activities	BARDA	CRO	Direct Labor	Fringe Rate	Material Costs	Other Direct Costs	Other Indirect Costs	Pass through Costs	Total
planner, if used, and assume 2 attendees per site, up to 8 CRO attendees and 4 BARDA attendees									
Site Initiation Visits		X							
Study Initiation Sub Total									
4. Site Monitoring and Management									
Interim monitoring visits		X							
Study site management		X							
Close out visits		X							
Manage investigator payments		X							
Site Monitoring and Management Sub Total									
5. Investigational product (IP) management									
Packaging, labeling, storage and distribution	X	X							
Authorization of initial IP shipment to sites	X								
Manage IP distribution and related documentation		X							
Verify IP documentation at sites, including dispensing records		X							
Perform IP accountability audits	X	X							
Retrieval or on-site disposal of IP		X							
IP management sub-total:									
6. Vendor Management									
Central laboratory: Select central laboratory, establish contract and make payments, manage central laboratory, develop		X							

Activities	BARDA	CRO	Direct Labor	Fringe Rate	Material Costs	Other Direct Costs	Other Indirect Costs	Pass through Costs	Total
laboratory database specs and visit specific laboratory requisitions, resolve all central laboratory lab issues with the sites; transfer central lab data to study database									
Interactive Voice Response System (IVRS)		X							
Select IVRS vendor, establish contracts and make payments, Manage IVRS contractor, develop IVRS database specifications and system menu, develop site IVRS manual; authorize subject eligibility verification and treatment assignment; transfer IVRS data to study database		X							
Vendor management sub-total									
7. Pharmacovigilance									
Development pharmacovigilance plan and safety database		X							
Provide 24 hour medical monitoring to all sites for all medical issues		X							
Collect information on SAEs from sites		X							
Prepare SAE narratives		X							
Submit expedited safety reports to regulatory authorities and sites		X							
Pharmacovigilance sub-total									
8. Data Management									
Develop data management plan		X							

Activities	BARDA	CRO	Direct Labor	Fringe Rate	Material Costs	Other Direct Costs	Other Indirect Costs	Pass through Costs	Total
Develop CRF; develop CRF completion instructions and monitoring guidelines		X							
Design database, prepare edit specifications		X							
Data/CRF review, query resolution to database lock		X							
Coding of baseline medical conditions, AEs, SAEs and concomitant medications		X							
Central laboratory data downloads		X							
AE/SAE listings and reconciliation with the Pharmacovigilance database		X							
Final database audit		X							
Data management sub-total									
9. **Biostatistics**									
Develop statistical analysis plan; specify number of tables, figures, and listings		X							
Develop randomization codes		X							
Final statistical analysis and statistical reports		X							
Biostatistics sub-total:									
10. Clinical study reports									
Preparation of the interim ICH-compliant clinical study report (assume 2 rounds of review prior to issuing final documents for signature by CRO and BARDA)		X							

Activities	BARDA	CRO	Direct Labor	Fringe Rate	Material Costs	Other Direct Costs	Other Indirect Costs	Pass through Costs	Total
Preparation of the final ICH-compliant clinical study report (assume 2 rounds of review prior to issuing final documents for signature by CRO and BARDA)		X							
Clinical study report sub-total:									
11. Project management and training									
Create Project Management and Monitoring Plan		X							
Project management		X							
Monthly project status reports		X							
BARDA/CRO team teleconferences: weekly during study start-up and enrollment and bi-weekly thereafter		X							
CRO internal teleconferences and meetings		X							
CRO team training		X							
Project management and training sub-total:									

Table 2 Summary of project activities and costs:

ACTIVITIES	Labor Costs	Pass Through Costs
1. Study and protocol planning		
2. Regulatory activities		
3. Study initiation		
4. Site monitoring and management		

5. Investigational product management		
6. Vendor management		
7. Pharmacovigilance		
8. Data management		
9. Biostatistics		
10. Clinical study report		
11. Project management and training		
Totals		
Fringe/Overhead/G&A		
GRAND TOTAL		

Attachment 1C – Statement of Work

MCM CSN TASK ORDER (TO) STATEMENT OF WORK (SOW)

as of {INSERT DATE}

Task Order Title: Randomized, Phase 2, Placebo-Controlled Study of the Safety, Reactogenicity, and Immunogenicity of Intramuscular Inactivated Influenza A/H5N1 Vaccine Given with Adjuvant in Healthy Adults

Background

Since 2004, HHS has acquired significant quantities of H5N1 antigen, as well as dose-sparing adjuvants. HHS seeks to expand the supply of influenza vaccine antigen available during a pandemic by the optimization of antigen content using adjuvants. This study supports this goal by determining if H5N1 vaccines acquired under HHS contract can be used safely and effectively with influenza vaccine adjuvants from other manufacturers during an influenza pandemic under EUA.

Statement of Work

Protocol Synopsis

Phase:	2
Population:	400 healthy male and female subjects aged 18 and 64 years old older
Number of Sites:	Up to 6 sites will enroll subjects in this study
Study Duration:	Approximately 14 months

Description of Agent or Intervention:

Two doses of inactivated influenza A/H5N1 vaccine delivered intramuscularly as 3.75 µg per dose or placebo with an adjuvant administered 21 days apart.

Objectives:

Primary Objectives

To examine the safety and tolerability of subvirion-inactivated H5N1 combined with the adjuvant in healthy adults.

To confirm that two doses of subvirion inactivated H5N1 vaccine with adjuvant meets CBER criteria for immunogenicity.

Secondary Objective

To evaluate the potential for development of antibodies cross-reacting with H5N1 viruses not included in the vaccine administered.

Endpoints

Primary Endpoints

- Frequency and severity of solicited (local and systemic reactogenicity) and unsolicited adverse event (AE) or serious adverse event (SAE) information (solicited in-clinic and via memory aids, concomitant medications, and periodic targeted physical assessment).

- Geometric mean titer (GMT) of hemagglutination inhibition (HAI) antibody titers against the H5N1 vaccine virus in each immunized group 21 days after receipt of the second dose of vaccine (approximately Day 42).

Secondary Endpoints

- Proportion of subjects achieving a serum hemagglutination (HAI) antibody titer of 40 or greater against the H5N1 vaccine virus in each immunized group 21 days after receipt of the second dose of vaccine (approximately Day 42).

- Frequency of 4-fold or greater increases of HAI antibodies against the H5N1 vaccine virus in each immunized group 21 days after receipt of the second dose of vaccine (approximately Day 42).

- GMT of neutralizing antibody titers against the H5N1 vaccine virus in each immunized group 21 days after receipt of the second dose of vaccine (approximately Day42).

- Proportion of subjects achieving a serum neutralizing antibody titer of 40 or greater against the H5N1 vaccine virus in each immunized group 21 days after receipt of the second dose of vaccine (approximately Day 42).

- Frequency of 4-fold or greater increases of neutralizing antibodies against the H5N1 vaccine virus in each immunized group 21 days after receipt of the second dose of vaccine (approximately Day 42).

- GMT, proportion achieving an HAI titer of 40 or greater, and frequency of 4-fold or greater increases in HAI antibody titers 7 months after receipt of the first dose of vaccine.

- GMT, proportion achieving a neutralizing titer of 40 or greater, and frequency of 4-fold or greater increases in neutralizing antibody titers 7 months after receipt of the first dose of vaccine.

Tertiary Endpoints

- Development of serum HAI and neutralizing HAI and neutralizing antibody responses against antigenically drifted variants of the H5N1 virus at all timepoints (day 0, 21, 42 and 7 months).

Description of Study Design

Approximately 400 healthy adults, 18 to 64 of age inclusive, will be enrolled into this randomized, placebo-controlled clinical trial. Subjects who meet the entry criteria for the study will be randomized 3:1 to receive two doses of intramuscular influenza A/H5N1 vaccine at 3.75 µg with adjuvant or placebo separated by 21 days. Subjects will be screened for health status by history, concomitant medications, vital signs (oral temperature, pulse and blood pressure) and complete physical examination (without genital and rectal exam) to include supraclavicular and axillary lymph node assessment within 21days prior to the first vaccination or on the day of, but prior to, first vaccination. Subjects must have an erythrocyte sedimentation rate (ESR) performed on a venous blood sample collected at screening (within 21 days prior to the first vaccination) or on the day of, but prior to, first vaccination, and the value must be confirmed as less than 30 mm per hour prior to randomization and first vaccination. All female

subjects of childbearing potential must have a negative urine or serum pregnancy test within 24 hours prior to receipt of each vaccination.

The first vaccination will occur on Day 0 and the second vaccination with occur approximately on Day 21. Vaccine reactions will be assessed for at least 30 minutes following each vaccination and continue through the Day 8-10 clinic visit following each vaccination. The vaccination site will be examined at the end of the 30 minute observation period following each vaccination as well as at the Day 8-10 clinic visit following each vaccination. Targeted physical exams may be performed if indicated based on review of interim health status prior to each vaccination as well as at the Day 8-10 clinic visit following each vaccination. Special attention will be given to the lymph node examination at baseline prior to vaccination (screening or Day 0), 8-10 days after each vaccination (approximately Days 8 and 29), approximately Day 21 prior to the second vaccination and approximately Day 42.

Subjects will be asked to record oral temperature, solicited vaccine reactions and any unsolicited AE/SAEs on a memory aid for 8 days (Days 0-7) following each vaccination. Subjects will be encouraged to take their temperature with a study issued thermometer around the same time each day. Study personnel will contact subjects by telephone at 1 to 3 days after each vaccination to review the memory aid, AE/SAEs and concomitant medications.

Adverse Events and concomitant medications will be assessed and targeted physical exams may be performed if indicated based on review of interim health status through 42 days after the first vaccination (approximately Day 42 for subjects who receive both doses of vaccine or approximately Day 21 for subjects who receive only one dose of vaccine).

Serious adverse events and new-onset chronic medical conditions will be assessed through 13 months after the first vaccination. Safety monitoring includes potential immune-mediated diseases (pIMD) a category of AEs that include autoimmune diseases and other inflammatory and/or neurologic disorders of interest which may or may not have an autoimmune etiology. Based on this information, subjects may be asked to return to clinic to be evaluated. Throughout the study, targeted physical exams may be performed if indicated based on review of interim health status since last visit or contact.

Venous blood samples for clinical laboratory evaluations (safety labs) will be collected from each subject prior to each vaccination and approximately 8 days after each vaccination. Venous blood samples for immunogenicity evaluations (HAI and neutralizing antibody titers) will be collected from each subject prior to each vaccination, approximately 8 and 21 days after each vaccination, and approximately 7 and 13 months after the first vaccination.

Inclusion Criteria for Study Entry and Dose 1

Subjects must meet all of the following inclusion criteria for study entry and to receive Dose 1:

1. Are males or non-pregnant females between the ages of 18 and 64 years, inclusive.

2. Women of child-bearing potential (not surgically sterile via tubal ligation, bilateral oophorectomy or hysterectomy or who are not postmenopausal for ≥1 year) must agree to practice adequate contraception that may include, but is not limited to, abstinence, monogamous relationship with vasectomized partner, barrier methods such as condoms, diaphrams, spermicides, intrauterine devices, and licensed hormonal methods during the study for at least 30 days following the last vaccination.

3. Are in good health, as determined by vital signs (oral temp, pulse and blood pressure), medical history to ensure any existing medical diagnoses or conditions are stable[2] and not considered clinically significant, and limited physical examination.

4. ESR less than 30 mm per hour.

5. Are able to understand and comply with planned study procedures.

6. Provide written informed consent prior to initiation of any study procedures.

Exclusion Criteria for Study Entry and Dose 1

Subjects who meet any of the following exclusion criteria at Screening/Baseline will be excluded from study participation:

1. Have a known allergy to eggs or other components of the vaccine (including gelatin, formaldehyde, octoxinol-9, thimerosal and chicken protein), or allergy to squalene-based adjuvants.

2. Have a positive urine or serum pregnancy test within 24 hours prior to vaccination (if female of childbearing potential as defined in Inclusion criterion 2), or women who are breastfeeding.

3. Have immunosuppression as a result of an underlying illness or treatment, or use of anticancer chemotherapy or radiation therapy (cytotoxic) within the preceding 36 months.

4. Have an active neoplastic disease or a history of any hematologic malignancy.

5. Have long term use of glucocorticoids including oral or parenteral prednisone or equivalent (≥ 2.0 mg/kg per day or ≥ 20 mg total dose) or high-dose inhaled steroids (>800 mcg/day of beclomethasone dipropionate or equivalent) within the preceding 6 months. (Nasal and topical steroids are allowed.)

6. Have a diagnosis of schizophrenia, bipolar disease, or other major psychiatric diagnosis.

7. Have been hospitalized for psychiatric illness, history of suicide attempt, or confinement for danger to self or others, within the past 10 years.

8. Are receiving psychiatric drugs*. Subjects who are receiving a single antidepressant drug and are stable for at least 3 months prior to enrollment, without de-compensating symptoms will be allowed to be enrolled in the study.

[2] Stable chronic medical condition – no change in prescription medication, dose, or frequency of medication in the last 3 months and health outcomes of the specific disease are considered to be within acceptable limits in the last 6 months. Any change that is due to change of health care provider, insurance company etc, or that is done for financial reasons, as long as in the same class of medication will not be considered a violation of this inclusion criterion. Any change in prescription medication due to improvement of a disease outcome will not be considered a violation of this inclusion criterion.

Appendix A: Schedule of Procedures/Evaluations

Study Visit	**Screen* 0**	**1**		**2**	**3**		**4**	**5**	**6**	**7**	
Study Day	**-28 to -1**	**0**	**2***	**8**	**21**	**V3+2***	**V3 +8**	**V3+28**	**208**	**365**	**Early Termination**
Procedure											
Informed Consent	X										
Review Eligibility Criteria	X	X			X						
Review Health Status				X	X		X	X		X	X
Vital Signs (Temp, Pulse, BP)	X	X			X						
Medical History	X	X									
Targeted Physical Examination, as indicated	X	X		X	X		X	X			X
Urinary pregnancy test	X†	X†			X†						
Assessment of lymph nodes	X	X		X	X		X	X			
Concomitant Medications	X	X	X	X	X	X	X	X			X
Blood for safety labs	X			X			X				
Blood for Antibody Assays		X		X	X		X	X	X	X	X
Randomization		X									
Vaccination		X			X						
Distribute Memory Aid and Study Related Materials		X			X						
Review Memory Aid			X	X		X	X				
SAE Assessment		X	X	X	X	X	X	X	X	X	X
AE Assessment		X	X	X	X	X	X	X			X

* Telephone call assessment

† Prior to vaccination

Deliverables & Schedule

Delivery #	**Deliverable Title**	**Format**[3]	**Timeframe for submission**
1	Draft protocol	MS Word	30 days prior to submission to CBER
2	Draft IND Submission package	MS Word	30 days prior to submission to CBER
3	Final protocol	Adobe Acrobat	Due: December 2013
4	Final IND Submission package	Adobe Acrobat	Due: December 2013
5	Interim report including a safety and immunogenicity for all subjects through Day 42 visit	Adobe Acrobat	30 days after all subjects complete Day 42 visit
6	SAEs	Email, telephone	Within 24 hours of SAE notification to CRO
7	Enrollment updates	MS PowerPoint	Weekly while enrollment is ongoing
8	Safety information specifically any several local or systemic reactions, Grade 3 or Grade 4 laboratory values	MS Word	Within 5 days of notification to the medical monitor
9	Investigator Brochure	Adobe Acrobat	Due: With the final protocol

[3] As specified, or compatible products with similar capabilities

10	Proposed Clinical Sites	Adobe Acrobat	Within 10 days of executed Task Order
11	Final Clinical Study Report	Adobe Acrobat	Within 3 months of database lock

Place of Performance

All work shall be at the contractor's site.

Period of Performance

The period of performance is anticipated to be not more than 26 months from Task Order award.

Security

Work performed is not anticipated to be classified above For Official Use Only

Government-Furnished Equipment (GFE)/ Government-Furnished Information (GFI)

Successful awardees are anticipated to use H5N1 antigen formulated with adjuvant produced by HHS under prior contracts to complete the objectives of this task order. The USG retains all rights to the material and information associated with that material.

Identification of Possible Follow-on Work.

None identified.

Identification of Potential Conflicts of Interest (COI).

Any situation that may influence which contractor should be awarded the TO. An "organizational COI" is a situation where because of other relationships or activities a person (company) is unable or potentially unable to render impartial assistance or advice to the Government or cannot objectively perform contract work or has an unfair competitive advantage. FAR 9.502 states that "an organization COI may result when factors create an actual or potential conflict of interest on an instant contract, or when the nature of the work to be performed on the instant contract creates an actual or potential COI on a future acquisition." An "organizational COI" exists when the nature of the work to be performed may, without some restriction on future activities, (1) result in an unfair competitive advantage to the contractor on MCM CSN work or on other contracts or (2) impair the contractor's objectivity in performing the contract work. In services contracts such as CRO Network, it is the latter which may most often occur because of a contractor's role as an advocate in contract performance or other situations. The primary burden is on the contractor to identify any organizational COI, however, the Government has the responsibility to identify and evaluate such conflicts. The CO is charged with avoiding, neutralizing or mitigating such potential conflicts.

COI will be explicitly addressed in RTOR submissions.

Packaging, Packing and Shipping Instructions.

None identified.

Inspection and Acceptance Criteria.

None identified.

GCP Compliance

Studies will be executed in compliance with FDA regulations.

Attachment 1E – Submission Instructions/Evaluation Criteria

Instructions

1) The submission instructions are designed to provide general guidance for preparing responses as well as providing specific instructions on response organization, format, and content. Respondents should include all documents and information requested and should be submitted in accordance with the instructions.
2) Respondents should submit a response that is self-sufficient and responds directly to the requirements of the Request for Task Order Response (RTOR). The response should be clear, concise, and include adequate detail for effective evaluation. The response should not simply rephrase or restate the Government's requirements, but rather provide convincing rationale to address how the respondent intends to meet the requirements of the RTOR. The response should contain sufficient information to enable the Government to fully evaluate and determine the respondent's capability to comply with the requirements identified in the RTOR.
3) Respondents shall submit a response that describes the procedures, processes, controls, etc. that are established for this RTOR. The respondent should provide any assumptions upon which your approach/solution is based, and the rationale supporting the assumption (i.e., why do you believe the assumptions are valid). Express your best understanding of the ramification inherent in the TO. Discuss alternatives considered, risks involved, impact to the missions (both detriment, as well as efficiency), impacts from external sources, etc. Provide any other explanations or supporting data (matrix, charts, or other graphics) determined necessary for the Government to fully understand the respondent's methodology and approach.
4) The respondent shall provide its response with a cover sheet that contains the company's name, address and telephone number, name and title of the person authorized to sign and negotiate the TO, offer validation period of sixty (60) days, RTOR number, and the original date of response. The original date shall be located in the upper right hand corner of the cover sheet.
5) Response Organization and Format: The response should consist of two (2) volumes. The volumes are: Volume 1 – Technical Submission and Volume 2 – Price Submission. All required copies are due by the closing date/time specified on the first page. Responses shall be submitted to the following address:

TOCO EMAIL ADDRESS

6) Responses must comply with the page limitations and format specified for each volume. Information submitted beyond limitations identified could negatively impact the evaluation during the rating process. The follow-on paragraphs provide the specific information required for each volume.

Volume	Format	Page Limitation	Number of Copies
Volume 1 – Technical Submission	MS Word or Adobe acrobat. Schedules and Gantt charts should be in MS Project or equivalent.	20 pages (Excluding the cover page and table of contents) (8.5 x 11 inch paper; no smaller than 11 font) Fold-outs used for charts, tables (May not exceed 11" x 17"; no smaller than 11 Font)	One E-mail copy
Volume II – Price Submission	MS Word and Price Data in Excel	15 pages (8.5 x 11 inch paper or 11x17 fold outs; 12 Font)	One E-mail copy

**All technical documents may be included in the same binder and on the same electronic media.*

- Format for responses to Volumes I and II must be as follows:
- A page is defined as one face of a sheet of paper containing information. Foldouts will be counted as two pages.
- Typing must be no smaller than size 11 font.
- The cover page, table of contents does not count against the page limitation.
- Elaborate formats, bindings or color presentations are not desired or required.

Volume 1 – Technical Submission.

Volume 1 should be clearly marked "Volume 1 - Technical Submission, {INSERT RTOR NUMBER}, and should include the respondent's technical submission. Volume 1 should consist of a written narrative that is the Respondents proposed solution to the requirement contained in the Statement of Objectives (SOO) for this TO. The technical discussion should be practical, straightforward, specific, concise, and complete. Technical submission should be segregated and partitioned into four separate sections, as described below. Each section should include a table of contents. A list of attachments, exhibits, tables, and figures, as required, may be provided. The table of contents will not count against the 20 page limitation. However any attachments, exhibits, tables, and figures will count against the 20 page limitation.

Volume 1 should not include price information.

Electronic versions of the price response should be submitted via email in MS Office Word format, and shall not be read only or password protected. All tables and links should be intact, and no links should exist to files not included with the response. Failure to comply with these formatting requirements may result in rejection of your response.

a) Technical Response: Respondents should demonstrate an understanding of the tasks required through a comprehensive discussion of each of the following:

i) Technical Approach. Respondent should demonstrate a thorough knowledge and understanding of how to fulfill the Government's requirement. The Offeror should present their concept for how to achieve objectives from the SOO/SOW, with results that provide best value to the Government and have potential utility towards the other objectives.

*Citations may include scientific literature (an Offeror summary of the relevance of selected citations is encouraged in this section), institutional quality control certifications, and other supporting data.

ii) Quality Assurance/Quality Control Plan. Respondent should demonstrate the quality system to be employed to accomplish the technical requirements of the SOO/SOW.

iii) Experience of Key Personnel. Respondent should demonstrate background and experience of key personnel relevant to the technical requirements of the SOO/SOW. If CVs for key personnel have been provided in the base contract, a one-paragraph biosketch will be sufficient for the task order response.

Volume 2 – Price Submission

The price submission should be clearly marked "**Volume 2, Price Submission, RTOR 0001**. To aide in the price submission evaluation, respondents are required to present their price information organized according to the following criteria.

a) The respondent shall include a price response substantially equivalent to the tables in Attachment 1B.
b) The respondent shall include a price response per the Contract Line Item Number (CLIN) Structure shown in Table 1. The respondent shall submit a completed CLIN Structure (Table 1).
c) The response shall include the labor/pricing matrix(ces) for the base period and the option periods using the format included in Table 2 below. In Table 2 respondent shall list all labor categories proposed for each major Section of the SOO/SOW by WBS number and title as proposed by the respondent. The labor/pricing matrix(ces) should include labor categories as identified in the Master Contract Section J, the number of full time equivalents (FTEs), the number of total hours per labor category, and the total dollar value. The respondent shall include a comparison between the labor categories/hourly rates proposed in this task order to your Labor/Pricing Matrix(ces) in the Master contract (See attachment 7).
d) Price submissions must be in the WBS format. Those that do not match Table 2 will be returned to the Offeror for correction
e) The Offeror shall provide all labor categories and labor rates for work under the prospective contract. The hourly rates proposed for each labor category shall be fully burdened rates, including any indirect or overhead rates applicable. The fully burdened hourly rates will be incorporated into any resultant contract awards under B.5. Advance Understandings, and must be used for budgeting task orders and reimbursement of labor costs.

Table 1 – CLIN Structure

(1) BASE PERIOD CLIN

CLIN #	Description of Option Item(s) -or- Option Service(s)	Estimated Cost or Price
0001	Base Period – Clinical Study Services and Technical Reports on Task Orders.	

Table 2 – Labor/Price Matrix

WBS 1.0 – (WBS title) Labor/Price Matrix				
Labor Category	Estimated Hours	Standard Hourly Rate	OH(%) or any other cost associated with total labor	Total Price
		$		$
		$		$
		$		$
		$		$
Labor Subtotal				$
Materials Cost				$
Other Direct Costs				$
Fee ($/%)			%	$
Grand Total				$

Table 3- Cost Centers

Cost Center	Unit	Price per Unit	Total Units	Total Cost
Eg. Pathology Slides	Slide	$1/slide	1000	$1000

Material(s) Matrix

Materials Base Year	Base Year Cost	Materials Option Year 1	Estimated Option Year 1 Cost	Materials Option Year 2	Estimated Option Year 2 Cost
Grand Totals					

Attachment 1E – Task Order Administration Information

Task Order Administration Information in this section will be incorporated into the Task Order contract.

Contract Number:	(completed by the Task Order Level Contracting Officer (TOCO) at time of TO award)
Task Order Number:	(completed by the TOCO at time of TO award)
Tracking Number:	(completed by the TOCO at time of TO issuance)
Follow-on to Contract and Task Order Number:	(If this is a follow-on order insert the contract number and the TO number to which it is a follow-on. If this is not for a follow-on order, state "Not Applicable")
Task Order Level CO Name:	(completed by the TM or TOCO at time of TO issuance)
Organization:	HHS/ASPR /AMCG
Address:	330 Independence Ave., SW – Room G640 Washington, DC 20201
Phone Number:	(completed by the TM or TOCO at time of TO issuance)
Fax Number:	(completed by the TM or TOCO at time of TO issuance)
E-Mail Address:	(completed by the TM or TOCO at time of TO issuance)

1. Technical Monitors (TMs) will serve as immediate points of contact specifically related to the technical component of the task order.

a. Primary TM.

Name:	(completed by the TM or TOCO at time of TO issuance)
Organization:	BARDA
Address:	330 Independence Ave SW, Room G640, Washington DC 20201
Phone Number:	(completed by the TM or TOCO at time of TO issuance)
Fax Number:	(completed by the TM or TOCO at time of TO issuance)
E-Mail Address:	(completed by the TM or TOCO at time of TO issuance)

b. Alternate TM.

Name:	
Organization:	BARDA
Address:	330 Independence Ave SW, Room G640, Washington DC 20201
Phone Number:	
Fax Number:	
E-Mail Address:	

ATTACHMENT #2

SAMPLE REQUEST FOR TASK ORDER RESPONSE 0002

Note: The Sample ROTRs are included for evaluation purposes only. No Task Order award will result from Offerors' Sample ROTR responses.

Date of Issue: **TBD**

Description of Services: Clinical Preparedness and Response to Orthopoxvirus Infections

Closing Date/Time: **TBD**

Dear Contractors:

This is a Request for Task Order Response (RTOR) for services to be provided under the Biomedical Advanced Research and Development Authority (BARDA) Medical Countermeasures Clinical Studies Network (MCM CSN) IDIQ contract vehicle. There is no incumbent contractor. Fair opportunity is herein provided to all BARDA MCM CSN prime contractors.

Attached are all related documents for this RTOR. Please ensure that you have read the attached documents, including specific response submission instructions that are included in this RTOR, and submit your response electronically by the date and time indicated above.

BARDA MCM CSN partners choosing not to submit a proposal shall provide an explanation of their decision to not submit a proposal no later than seven (7) business days after receipt of this official RTOR.

All replies should be directed via e-mail to {INSERT TOCO/TOCS NAME} and {INSERT BACKUP TOCO/TOCS NAME}. All items within the RTOR must be completed and returned by closing due date and time.

In addition to this letter, this RTOR includes the following exhibits:

Attachments

- ☒ Attachment 2A – Additional Terms and Conditions
- ☒ Attachment 2B – Pricing Schedule/CLIN Structure
- ☒ Attachment 2C – Statement of Work and/or Statement of Objectives
- ☐ Attachment 2D – Risk Register
- ☒ Attachment 2E – Submission Instructions/ Evaluation Criteria
  - ☒ 5 A – Instructions
  - ☒ 5 B – Evaluation Criteria
  - ☒ 5 C – Basis for Award
- ☐ Attachment 2F – Task Order Administration Information
- ☐ Attachment 2G – Past Performance Evaluation Form

Contract Type

The Government contemplates award of the following contract type:

☐ Cost Reimbursement ☐ Firm Fixed Price ☒ Mixed Cost Reimbursement/Firm Fixed Price

Anticipated Period of Performance
24 months from date of task order award with three 12 month option periods

Location of Performance
Contractor provided facilities.

Additional Instructions
The task order contracting officer (TOCO) reserves the right to withdraw and cancel this RTOR. In such an event, contractors shall be notified in writing of the TOCO's decision. This decision is final, conclusive and shall not be subject to the "Disputes" clause or the "Contract Disputes Act."

Your response must be in full compliance with the instructions in this RTOR and your basic contract. The response (to include price) shall be valid for sixty (60) calendar days. If you have any questions, please contact *{INSERT TOCO/TOCS NAME}* via email at *{INSERT TOCO/TOCS E-MAIL}* and copy *{INSERT BACKUP TOCO/TOCS NAME}* via email at *{INSERT BACKUP TOCO/TOCS E-MAIL}*

{INSERT TOCO NAME}

Task Order Contracting Officer

BARDA MCM CSN Request for Task Order Response (RTOR)
[Insert Date]

Notice to All MCM CSN Contractors:
This Request for Task Order Response is being issued to invite proposals to develop a preparedness and clinical study response capability for an emergency event requiring treatment of Orthopoxvirus Infections. The objective of this RTOR is to establish the initial components necessary to conduct a clinical study during a smallpox event, including the preparedness package and clinical trial response plan. The package would consist of Preparedness and Response components.

This RTOR provides key timelines, parameters and assumptions for the preparation and conduct of the study.

The protocol design is subject to further discussions with the FDA and may be amended. Respondents are requested to provide an initial proposal and cost estimates based upon the enclosed information. The budget proposal should be prepared and submitted to show the tasks outlined in Table 1, Attachment 2 and Attachment 3. Add additional or supplementary information to clarify any assumptions that you have used and to describe the processes and procedures that you would use. Please provide your budgets in the format in Attachment 2. Please include any suggestions you may have in conducting this study based on prior experience. If you plan to use a subcontractor for any tasks, please specify the vendor or describe the process for vendor selection and include the flow of how work will progress with the selected vendor(s).

Along with the proposal, please provide a organizational chart of the proposed project team including CVs for your proposed program director, project manager, medical monitor, data management project

manager, biostatistician, and other key members of your proposed team for those activities planned to start in **1Q2014**. Define the full time equivalent (FTE) commitment that each key team member will provide to BARDA for this project.

Base Period: Preparedness:
Develop and provide a plan that is ready to execute for the trial to include but not limited to personnel, documentation, regulatory approvals, material and management plans as appropriate

- Provide Clinical Protocol (CPs)
- Provide Case Report Forms (CRFs)
- Provide Informed Consent forms (ICFs)
- Develop a clinical and safety database in preparation for Clinical database readiness
- Pre-identify clinical research sites including study budget and contracts in place
- Pre-qualify central laboratories for validated assays
- Provide documented product delivery, storage and pharmaceutical product accountability procedures
- Obtain Institutional Review Board (IRB) approval of the clinical protocols, annotated CRFs and ICFs. (National IRB if available/appropriate)
- Establish an identified project team. The project team may include a clinical research associate, safety monitor, data manager, regulatory specialist, medical writer, project manager and pharmacovigilance specialist.
- Document data flow and sample handling processes (lab manual)
- Annual review and renewal of the plan
- Test the capability of the plan to complete first patient, first dose within 24 hours in a 72 hours table-top exercise.

Option Period: Response
Execute the plan to treat the first patient with the first dose within 24 hours of the unilateral execution of this option.

1. Initiation of the clinical trial using the investigational oral antiviral drug within 24 hours of TO Option award.
2. Gather clinical data.
3. All the components needed to monitor individuals dosed with an investigational oral antiviral drug during a smallpox event. Including, but is not limited to: Drug supply monitoring, case report form handling/monitoring, sample tracking for smallpox virus viral burden and

pharmacokinetic testing, pharmacovigilence/safety monitoring, database maintenance and clinical report generation.

Protocol Summary

Full Title	A Research Protocol for the Anti-Orthopoxvirus Compound when Administered Orally for a Minimum of 14 Days to Individuals Post Exposure to a Smallpox Outbreak and/or Presenting with Manifestations of Smallpox Disease NOTE: This protocol is intended to support clinical research during an emergency use of an unapproved drug. The investigational drug is currently being studied in adequately controlled safety clinical trials and has been authorized for emergency use under an **EUA** emanating from a smallpox outbreak.
Short Title	BARDA-ORTHOPOX-READINESS-0001
Clinical Agent Provided by	Centers for Disease Control
Clinical Agent Manufactured by	Investigational Drug Manufacturer
IND Sponsor (if applicable)	Centers for Disease Control
Treatment Population	Patients with confirmed orthopoxvirus infections or patients that require secondary treatments of complications of vaccinia infection resulting from vaccination, secondary transmission, or other exposure.

Protocol Design	A clinical research protocol allowing treatment, or post-exposure treatment, of a patient with the investigational drug at an approved daily oral dose for a minimum of 14 days. The total number of patients enrolled will depend on the number of eligible patients (to include all adults, pregnant and nursing women and children) who consent/assent to receiving the investigational drug. The location and number of sites will be determined based on the location of the smallpox infection outbreak. The health status, medical history and physical examination will be recorded. Photographs of affected areas will be taken at baseline and may be requested weekly during and after treatment with the investigational drug. Treated patients will have urine and blood samples taken at various time points during the study (see Schedule of Events table). Eligible patients will receive the approved dosage of the investigational drug daily for a minimum of 14 days.
Duration of Treatment and Follow Up	Duration of treatment for each patient will be a minimum of 14 days followed by at least a 30 day follow-up period.
Medication Description	Investigational drug capsules are bi-color hard gelatin capsules containing white to off-white powder. The strength of each capsule is one-third the daily oral dose.
Primary Objective	To allow the use of investigational drug for the primary and secondary treatment of confirmed and suspected orthopoxvirus infections.
Secondary Objective	To evaluate the efficacy, safety, and tolerability of the investigational drug based on clinical parameters when administered orally as a single daily dose for a minimum of 14 days in patients with smallpox infection or exposure to smallpox.

Endpoints	The primary endpoint will be the efficacy and safety of the unapproved drug. The secondary endpoints will be efficacy assessments based on the resolution of signs and symptoms of smallpox infection or prevention of clinically apparent smallpox infection. At manageable intervals, anti-orthopox immunoglobulin levels will be obtained in order to check for the occurrence of sub-clinical infections. Photographs of affected areas of 25 subjects will be taken in a digital format to follow lesion progression and healing in patients. Safety assessments will be made at intervals during treatment to evaluate adverse reactions. These may include systemic, hematologic, clinical, and chemical assessments.
Number of CRF pages per subject	Approximately 32
Randomization	There is no randomization schema; all eligible patients will receive the investigational drug.

Additional Information

Timeline: **24 hours from execution of the option to execute the study to First Patient First Dose.**

Contract Type(s): **Firm Fixed Price**

Contract Duration: **24 months with three 1 year options**

Security Requirements: **None**

Instructions to Offerors

General: This acquisition is being conducted under FAR 16.505; therefore, the contracting techniques under FAR part 15.3 do not apply. As such, the government is not obligated to determine a competitive range, conduct discussions with all contractors, or solicit final revised proposals. Offerors will be required to provide a cost/price and technical proposal in accordance with the instructions herein.

Cost/Price Proposal: Contractors are required to provide a cost/price proposal. Cost/price proposal must include a completed Attachment 2A. Proposals should address the Offeror's technical approach, skill mix and hours, hourly rates, estimated travel, Other Direct Costs (ODCs), and total price.

The cost proposal should be sufficiently detailed to allow comprehensive understanding of cost reasonableness and realism. Supporting information for each cost element should be provided, including, but not limited to, Direct Labor, Fringe Benefits, Overhead, General and Administrative (G&A) expenses, Facilities Capital Cost of Money, Other Direct Costs and Profit consistent with your cost accounting system, provisional billing rates, and forward pricing rate agreements.

Technical Proposal

Fonts should not exceed 14 pts, and be no smaller than 11 points. Page margins should be no smaller than 1 inch. Pages should be 8.5" x 11". The technical proposal shall not exceed 20 pages in length. The business proposal should not exceed 15 pages in length. Gantt charts should be provided in native Microsoft project (or equivalent) format.

Your technical proposal should include the following:

Part A: Technical Approach

Technical approach to achieving the objectives of this RTOR.

Roles and responsibilities matrixes or clearly define roles in Part B: Experience of Key Personnel.

Contract Work Breakdown Structure.

Gantt chart including at a minimum the major tasks and critical subtasks.

Part B: Experience of Key Personnel

Provide Resumes of Key Personnel (include skills, required certifications if required by contract; relate resume experience to the required functional areas of the project.)

Part C: Gap Testing Plan

Approach to gap test the ready to execute plan within 24 hours via a 72 hour table-top exercise.

Conflict of Interest

Any contractor (or member of its team and /or subcontractor) having a conflict of interest as defined under FAR Part 9.5 must identify the conflict as soon as it is known and provide a recommended mitigation plan. Mitigation plans are required whenever a competing contractor has had unequal access to non-public information regarding the Task Order requirement, or has assisted the Government in defining the Task Order requirements or evaluation criteria.

Attachment 2A – Additional Terms and Conditions

The following provision is added to this RTOR:

Contractor's additional information

The contractor shall provide all personnel, management, supervision, equipment, tools, supplies, materials, transportation, and any other items and services necessary to perform the functions of the Statement of Work (SOW). The place of performance is: the contractor's facilities.

Inspection and Acceptance Inspection and acceptance of all work, performance, reports and other deliverables under this task order will be performed at the location specified in this RTOR by the Technical Monitor (TM). TMs are responsible for inspection of services under the Task Order (TO). The Government will record all surveillance observations. When an observation indicates defective performance, the TM will request the contractor's representative to initial the observation.

Deliveries or Performance **24** months from date of task order award with three 12 month option periods

Task Order Administrative Data.

Task Order Contracting Officer (TOCO) The Acquisitions Management Contracts and Grants Office (AMCG) is responsible for awarding this TO. The TOCO is {INSERT TOCO NAME}, {INSERT TOCO PHONE NUMBER}, {INSERT TOCO E-MAIL ADDRESS}.

TOCO Points of Contact The TOCO will be responsible for the administration of this TO and, alone, is authorized to take actions on behalf of the Government that result in changes in the terms and conditions of the TO. TOCO is {INSERT TOCO NAME}, {INSERT TOCO PHONE NUMBER},{INSERT TOCO E-MAIL ADDRESS}.

Technical Monitor (TM)

The Task Order Contracting Officer (TOCO) will designate a representative called the Technical Monitor (TM). The TM will be designated in writing to act as the TOCO representative in monitoring specified aspects of contractor performance, and a copy of the designation will be furnished to the Contractor. These aspects may include ensuring that the contractor's performance meets the standards set forth in the Task Order (TO), ensuring the contractor meets the technical requirements under the TO by the delivery date(s) and/or within the period of performance, and ensuring that the contractor performs within the price or estimated cost stated in the TO. The Contractor is cautioned to read the designation because certain authority under the TO is reserved solely for the TOCO. The term "Task Order Contracting Officer (TOCO)" as used throughout the TO shall be interpreted to include the designated Technical Monitor (TM) acting within the limits of their delegation of authority.

The TM will act in a liaison capacity to coordinate activities between the Contractor and the Government as required in the performance of the work under this TO.

No oral statements of any person whosoever will in any manner or degree modifies or otherwise affects the terms of this TO. The TOCO is the only person authorized to approve changes in any of the

requirements under this TO, and notwithstanding any provisions contained elsewhere in this TO, the said authority remains solely with the Task Order Contracting Officer.

The TM will receive, review, approve, sign and submit the invoice to the TOCO to initiate contractor payment. Additional information will be provided in the awarded TO.

Prompt Payment Act: The due date for making an invoice payment is as follows: The 30th day after the designated billing office receives a proper invoice from the contractor.

Special Task Order Requirements. For example: “The Offeror shall propose a technical approach including a statement of work (SOW) that will achieve objectives 1 and 2 from the statement of objectives (SOO). Additional objectives are present in the SOO, but are for reference only at this time. Objectives 1 and 2 should be satisfied such that the products would ultimately be useful for satisfying other objectives, but no work on these other objectives is to be proposed in response to this request.”

All applicable contract clauses from the main IDIQ contract flow down to this CRO Network Task Order.

Attachment 2B – Pricing Schedule/CLIN Structure

Table 1. Cost and Price Schedule:

Activities	HHS/ BARDA	CRO	Direct Labor	Fringe Rate	Material Costs	Other Direct Costs	Other Indirect Costs	Pass through Costs	Total
12. Study and Protocol Planning									
Clinical Protocol and ICF template	X	X							
Site Procedures Manual Preparation and distribution to sites		X							
Investigator Brochure preparation	X								
Investigator Brochure distribution to sites		X							
Study Protocol and Planning Sub Total:									
13. Regulatory activities:									
Preparation and collection of investigator regulatory document packages		X							
Trial Master File Preparation and Maintenance		X							
Central/National IRB submission & Approval	X	X							
Regulatory activities Sub-Total									
14. Site Initiation									
Site identification and screening	X	X							
Pre-study site qualifications visits		X							
Site selection	X	X							
Investigator contract template		X							

development, distribution, budget negotiation, and contract establishment with sites									
Investigator meeting planning, attendance and conduct. Include pass through costs for meeting planner, if used, and assume 2 attendees per site, up to 8 contractor attendees and 4 HHS/ BARDA attendees and guests		X							
Site Initiation Visits		X							
Study Initiation Sub Total									
15. Site Monitoring and Management									
Interim monitoring visits		X							
Study site management		X							
Close out visits		X							
Manage investigator payments		X							
Site Monitoring and Management Sub Total									
16. Investigational product (IP) management									
Packaging, labeling, storage and distribution	X								
Authorization of initial IP shipment to sites	X								
Manage IP distribution and related documentation	X	X							
Verify IP documentation at sites, including dispensing records		X							
Perform IP accountability audits	X	X							

Retrieval or on-site disposal of IP		X							
IP management sub-total:									
17. Vendor Management									
Central laboratory: Select central laboratory, establish contract and make payments, manage central laboratory, develop laboratory database specs and visit specific laboratory requisitions, resolve all central laboratory lab issues with the sites; transfer central lab data to study database		X							
Interactive Voice Response System (IVRS)		X							
Select IVRS vendor, establish contracts and make payments, Manage IVRS contractor, develop IVRS database specifications and system menu, develop site IVRS manual; authorize subject eligibility verification and treatment assignment; transfer IVRS data to study database		X							
Vendor management sub-total									
18. Pharmacovigilance									
Development pharmacovigilance plan	X	X							
Development of the safety database		X							
Provide 24 hour medical monitoring to all sites for all medical issues		X							

Collect information on SAEs from sites		X							
Prepare SAE narratives		X							
Submit expedited safety reports to regulatory authorities and sites		X							
Pharmacovigilance sub-total									
19. Data Management									
Develop data management plan		X							
Finalize the development of CRF	X	X							
Develop CRF completion instructions and monitoring guidelines		X							
Design database, prepare edit specifications		X							
Data/CRF review, query resolution to database lock		X							
Coding of baseline medical conditions, AEs, SAEs and concomitant medications		X							
Central laboratory data downloads		X							
AE/SAE listings and reconciliation with the Pharmacovigilance database		X							
Final database audit		X							
Data management sub-total									
20. **Biostatistics**									
Develop statistical analysis plan; specify number of tables, figures, listings		X							

Develop randomization codes		NA							
Final statistical analysis and statistical reports		X							
Biostatistics sub-total:									
21. Clinical study reports									
Preparation of the interim ICH-compliant clinical study report (assume 2 rounds of review prior to issuing final documents for signature by CRO and BARDA)		X							
Preparation of the final ICH-compliant clinical study report (assume 2 rounds of review prior to issuing final documents for signature by CRO and BARDA)		X							
Clinical study report sub-total:									
22. Project management and training									
Project management & project management Plan (to include readiness & response strategy		X							
Monthly project status reports		X							
BARDA/CRO team teleconferences: weekly during study start-up and enrollment and bi-weekly thereafter		X							
CRO internal teleconferences and meetings		X							
CRO team training		X							
Project management and training sub-total:									

Table 2 Summary of project activities and costs:

ACTIVITIES	Labor Costs	Pass Through Costs
12. Study and protocol planning		
13. Regulatory activities		
14. Study initiation exercise(s)		
15. Study initiation		
16. Site monitoring and management		
17. Investigational product management		
18. Vendor management		
19. Pharmacovigilance		
20. Data management		
21. Biostatistics		
22. Clinical study report		
23. Project management and training		
Totals		
Fringe/Overhead/G&A		
GRAND TOTAL		

Attachment 2C – Statement of Work

MCM CSN TASK ORDER (TO) STATEMENT OF WORK (SOW)

as of {INSERT DATE}

Task Order Title: Clinical Trials Capabilities Preparedness and Response to a Biothreat of Orthopoxvirus Infections

Background

One of the highly communicable and potentially lethal infections caused by orthopoxviruses is smallpox. Variola viruses, the etiological agents of smallpox, cause two clinical forms of smallpox, variola major and variola minor, distinguished largely by case fatality rates. Variola major is the most common and more severe form of smallpox, often with more extensive rash and higher mortality rates.

While vaccination is the primary mode for prevention of orthopoxvirus infections, there are currently no FDA-approved drugs for the treatment of smallpox or other serious orthopoxvirus. Vaccination must occur soon after exposure to be effective in preventing or reducing the seriousness of the disease caused by orthopoxvirus infections. An effective treatment of smallpox would be imperative in the event of an intentional act of bioterrorism involving orthopoxvirus such as variola since many individuals could become infected. In such an event, a therapeutic intervention in addition to vaccine would prove beneficial to treat disease in patients with disease progression too severe to benefit from vaccination.

HHS/BARDA has advanced the developmental status of orally available small molecule smallpox therapeutic. The investigational oral antiviral product is currently under development, for the treatment of smallpox. A supply of this investigational drug has been acquired by HHS for use in the event of a biothreat of Orthopoxvirus infections. During the emergent event, it will be necessary to collect clinical safety and efficacy data on the use of the investigational product.

Statement of Objectives

An IND protocol for the use of the investigational drug for treatment of Human Orthopoxvirus infections has been approved by the FDA. The awardees are requested to develop a comprehensive strategy for preparedness and execution plan during an emergency. The plan will include all the components necessary to collect data and monitor individuals dosed with the investigational drug during the Smallpox event. The comprehensive strategy will specify all preparation and readiness activities, including but not limited to drug supply monitoring, case report form monitoring, sample tracking for Smallpox virus viral burden and pharmacokinetic testing, pharmacovigilance/safety monitoring and reporting, database maintenance, clinical report generation and the establishment of a Smallpox Emergency Medical Team (SEMT).

Protocol Synopsis

Phase: 3 (Expanded Access)

Population: All patients who consent to receiving the investigational drug treatment under the IND treatment program.

Number of Sites: The number and location of sites will be determined by the location and severity of the biothreat of Orthopoxvirus infections

Description of Agent: the investigational drug (tecovirimat monohydrate) is an inhibitor of orthopoxvirus release. The approved dose will be given daily for a minimum of 14 days.

Intended Use:

Primary treatment for orthopoxvirus infections including variola (smallpox), vaccinia, monkeypox, and cowpox that are confirmed by laboratory diagnostic testing or suspected based on known exposure(s) and /or clinical manifestations of disease, while laboratory confirmation may be pending.

Secondary treatment of complications of vaccinia infection (e.g. serious inadvertent inoculation with vaccinia, eczema vaccinatum, severe generalized vaccinia, or progressive vaccinia) resulting from vaccination, secondary transmission, or other exposure.

Schedule of Events

Days / **Parameters**	**Pre-Treatment Period**	**Treatment Period**					**Post Treatment Period**	
	Prior to first dose (< 24 hours)	**Day 1**	**Day 2-14**	**Day 7**	**Day 14**	**Every 7 Days Thereafter, if still on Beyond 14 Days**	**7 Days After Last Dose**	**30 Days After Last Dose**
Signed Informed Consent	X							
Inclusion/Exclusion	X							
Medical History	X							
Summary of Clinical Status/Progress				X	X	X	X	X
Concomitant-Medications[a]	X	X	X			X		
Physical examination	X			X	X	X		
Vital Signs[b]	X			X	X	X		
Hematology[c]	X			X	X	X		
Chemistry[d]	X			X	X	X		
Immunochemistry[e]	X			X	X	X	X	X
Urinalysis[f]	X			X	X	X		
Lesion Sampling[g]	X				X	X		
Lesion Photos[h]	X	X		X	X	X	X	
Lesion Photos (no regression after 3 days)	X	X	X		X		X	
PK Samples[i]		X	X		X	X		
Adverse Events[j]		X	X	X	X	X	X	X

[a] Concomitant medications will be recorded from 24 hrs before the first dose of the investigational drug until the last dose of the investigational drug, if possible.
[b]Vital signs will include weight, BP, HR, RR, temp, and height (only once).
[c]Hematologic parameters will include PT and PTT, platelet count, Hgb, HCT, RBC, absolute WBC, and differential count.
[d]Chemistry parameters will include Ca, Mg, Na, K, Cl, HCO3, P, urea, creatinine, calculated CrCl, glucose, UA, albumin, TBil, total protein, ALT, AST, and ALP.
[e]Immunochemistry parameters will include orthopoxvirus immunoglobulins, IgM and IgG.
[f]Urinalysis parameters will include protein, Hgb, glucose and microscopic analysis.
[g]Lesion sampling will be performed based on patient's clinical presentation and progression (e.g. based on evaluation of digital photos)
[h]Digital photos of lesions on a standardized part of the body will be taken weekly or daily if regression is not seen after the first three days.
[i]PK samples for patients should be taken 1 hour before and 4 hours after the dose on days 1, 7 and 14 (i.e. dose # 1, dose #7, and dose #14), then every 7 days thereafter, if the duration of therapy extends beyond 21 days.
[j]SAEs should be recorded immediately and reported within 24 hours of occurrence.

Example Deliverables & Schedule

Offerors may propose this or another deliverable schedule as best suits their concept of preparedness and executing a Clinical Study during a public health emergency.

Deliverable #	Deliverable Title	Format[4]	Quantity	Timeframe for submission
Preparedness Tasks				
1	Write procedures and initial training materials	Submit drafts to BARDA for review and approval; provide final copy	4	
2	Develop and Apply a Readiness maintenance List	Hold first annual meeting to review	1	
3	Data Management Plan	Written document	1	
4	Pharmacovigilance Plan	Written plan delivered	1	
5	Specimen Processing Plan	Written plan delivered	1	
6	Proposed Clinical Sites	Adobe Acrobat		Within 10 days of executed Task Order
7	Plan and hold initial training course with	Complete training	1	

[4] As specified, or compatible products with similar capabilities

	Contractor SEMT and BARDA designees			
8	Update SEMT training materials	Annual review and update; refresher course held	1	
9	Pre-qualify a laboratory for unapproved drug Pharmacokinetic Assay Capabilities	Provide pre-qualification report	1	
10	Sub-contract for unapproved drug Pharmacokinetic Assay and reporting capabilities to be maintained at the pre-approved laboratory	Provide subcontractor SOW and submit request for COA	1	
11	Perform annual "re-qualification" of the laboratory	Annual report	1	
12	Finish Database Build	Demonstrate Database Capabilities in a webinar	1	
13	Identify a IRB(s) to cover national emergency;	Provide written plan of Ethic Committee Approval	1	
14	Review CP, CRFs, IB and IC	Written comments	1	
15	Identify initial members of the SEMT. Obtain consent and vaccinate the SEMT team	Provide CVs and signed informed consent copies	2 Copies to TM; Letter Only to CO	
16	Quarterly teleconferences (after Readiness Phase is complete)	Hold Teleconferences and provide minutes	1	
Execution Tasks				
17	Obtain IRB Approval to cover national emergency	Provide written letter from IRB on Preparedness	4	

		position/Approval		
18	SAE reporting	Email, telephone	As required	Within 24 hours of SAE notification to contractor
19	Enrollment updates	MS PowerPoint	1	Weekly while enrollment is ongoing
20	Finalized Draft Clinical Study Report	Adobe Acrobat	1	Within 3 months of database lock
21	Monthly Status Report	Contractor-Determined Format	1	
22	Draft Monitoring Plan	Deliver Final MP for BARDA approval	1	
23	Final clinical study report	Deliver final report	1	

Place of Performance

The majority of work will be performed at the Contractor's site. The kick-off and annual meetings would be held face to face. The SEMT members, contractor support staff and BARDA designees would be expected to attend the kick-off and annual meetings. The Contractor would host the meetings at their facilities and their staff would travel as needed.

The SEMT members will be expected to travel immediately to the site of the Smallpox outbreak and remain at that site until the outbreak has been contained or the event is better characterized.

Period of Performance

It is expected that the "Preparedness Phase" may require up to 365 calendar days after the TO award. A meeting will be held about 60 days before the end of the Preparedness Phase to assess whether sufficient progress has been achieved on the deliverables. Each subsequent year will be considered a Readiness year and will be structured as a contract option. About 60 days prior to the end of each Readiness year, a meeting will be held to determine whether the deliverables have been received, the quality and effectiveness of the staffing and resources has been maintained and performance warrants exercising an option for another Readiness year.

Security

In general, the work to be performed must be treated as For Official Use Only. The Task Manager will provide a task order-level security restraints or releasability constraints that will have an effect on performance of the tasks defined in the SOW.

Government-Furnished Equipment (GFE)/ Government-Furnished Information (GFI)

Successful awardees are anticipated to use H5N1 antigen formulated with adjuvant produced by HHS under prior contracts to complete the objectives of this task order. The USG retains all rights to the material and information associated with that material.

Other Pertinent Information or Special Considerations

All plans, procedures and activities should be written and executed using the spirit of Good Clinical Practice and Good Laboratory Practice.

Identification of Possible Follow-on Work.
Awardees of this task are required to include the execution of the clinical trial response plan as an optional task in a response to this RTOR.

Identification of Potential Conflicts of Interest (COI).
Any situation that may influence which contractor should be awarded the TO. An "organizational COI" is a situation where because of other relationships or activities a person (company) is unable or potentially unable to render impartial assistance or advice to the Government or cannot objectively perform contract work or has an unfair competitive advantage. FAR 9.502 states that "an organization COI may result when factors create an actual or potential conflict of interest on an instant contract, or when the nature of the work to be performed on the instant contract creates an actual or potential COI on a future acquisition." An "organizational COI" exists when the nature of the work to be performed may, without some restriction on future activities, (1) result in an unfair competitive advantage to the contractor on MCM CSN work or on other contracts or (2) impair the contractor's objectivity in performing the contract work. In services contracts such as MCM CSN, it is the latter which may most often occur because of a contractor's role as an advocate in contract performance or other situations. The primary burden is on the contractor to identify any organizational COI, however, the Government has the responsibility to identify and evaluate such conflicts. The CO is charged with avoiding, neutralizing or mitigating such potential conflicts.

COI will be explicitly addressed in RTOR submissions.

Packaging, Packing and Shipping Instructions.
None identified.

Inspection and Acceptance Criteria.
None identified.

GCP Compliance
Studies will be executed in compliance with FDA regulations.

Attachment 2E – Submission Instructions

Instructions

1) The submission instructions are designed to provide general guidance for preparing responses as well as providing specific instructions on response organization, format, and content. Respondents should include all documents and information requested and should be submitted in accordance with the instructions. The respondent is cautioned to follow the instructions carefully, as the Government reserves the right to make an award based on initial responses received without discussion of such response.
2) Respondents should submit a response that is self-sufficient and responds directly to the requirements of the Request for Task Order Response (RTOR). The response should be clear, concise, and include adequate detail for effective evaluation. The response should not simply rephrase or restate the Government's requirements, but rather provide convincing rationale to address how the respondent intends to meet the requirements of the RTOR. The response should contain sufficient information to enable the Government to fully evaluate and determine the respondent's capability to comply with the requirements identified in the RTOR.
3) Respondents shall submit a response that describes the procedures, processes, controls, etc. that are established for this RTOR. The respondent should provide any assumptions upon which your approach/solution is based, and the rationale supporting the assumption (i.e., why do you believe the assumptions are valid). Express your best understanding of the ramification inherent in the TO. Discuss alternatives considered, risks involved, impact to the missions (both detriment, as well as efficiency), impacts from external sources, etc. Provide any other explanations or supporting data (matrix, charts, or other graphics) determined necessary for the Government to fully understand the respondent's methodology and approach.
4) The respondent shall provide its response with a cover sheet that contains the company's name, address and telephone number, name and title of the person authorized to sign and negotiate the TO, offer validation period of sixty (60) days, RTOR number, and the original date of response. The original date shall be located in the upper right hand corner of the cover sheet.
5) Response Organization and Format: The response should consist of two (2) volumes. The volumes are: Volume 1 – Technical Submission and Volume 2 – Price Submission. All required copies are due by the closing date/time specified on the first page. Responses shall be submitted to the following address:

TOCO EMAIL ADDRESS

6) Responses must comply with the page limitations and format specified for each volume. Information submitted beyond limitations identified could negatively impact the evaluation during the rating process. The follow-on paragraphs provide the specific information required for each volume.

**All*

Volume	Format	Page Limitation	Number of Copies
Volume 1 – Technical Submission	MS Word or Adobe acrobat. Schedules and Gantt charts should be in MS Project or equivalent.	20 pages (Excluding the cover page and table of contents) (8.5 x 11 inch paper; no smaller than 12 font) Fold-outs used for charts, tables (May not exceed 11" x 17"; no smaller than 11 Font)	One E-mail copy
Volume II – Price Submission	MS Word and Price Data in Excel	15 pages (8.5 x 11 inch paper or 11x17 fold outs; no smaller than 11 Font)	One E-mail copy

technical documents may be included in the same binder and on the same electronic media.

- Format for responses to Volumes I and II must be as follows:
- A page is defined as one face of a sheet of paper containing information. Foldouts will be counted as two pages.
- Typing must be no smaller than size 11 font.
- The cover page, table of contents does not count against the page limitation.
- Elaborate formats, bindings or color presentations are not desired or required.

Volume 1 – Technical Submission.

Volume 1 should be clearly marked "Volume 1 - Technical Submission, {INSERT RTOR NUMBER}, and should include the respondent's technical submission. Volume 1 should consist of a written narrative that is the Respondents proposed solution to the requirement contained in the Statement of Objectives (SOO) for this TO. The technical discussion should be practical, straightforward, specific, concise, and complete. Technical submission should be segregated and partitioned into four separate sections, as described below. Each section should include a table of contents. A list of attachments, exhibits, tables, and figures, as required, may be provided. The table of contents will not count against the 20 page limitation. However any attachments, exhibits, tables, and figures will count against the 20 page limitation.

Volume 1 should not include price information.

The Technical Proposal must be included in both hard copy and electronic format. Electronic versions of the price response should be submitted via email and on a CD/USB Drive in MS Office Word format, and shall not be read only or password protected. All tables and links should be intact, and no links should exist to files not included with the response. The hard copy version will take precedence for any differences noted between the hard and electronic versions of a response. Failure to comply with these formatting requirements may result in rejection of your response.

a) Technical Response: Respondents should demonstrate an understanding of the tasks required through a comprehensive discussion of each of the following:

i) Technical Approach. Respondent should demonstrate a thorough knowledge and understanding of how to fulfill the Government's requirement. The Offeror should present their concept for how to achieve objectives from the SOO/SOW, with results that provide best value to the Government.

*Citations may include scientific literature (an Offeror summary of the relevance of selected citations is encouraged in this section), institutional quality control certifications, and other supporting data.

ii) Quality Assurance/Quality Control Plan. Respondent should demonstrate the quality system to be employed to accomplish the technical requirements of the SOO/SOW.

iii) Experience of Key Personnel. Respondent should demonstrate background and experience of key personnel relevant to the technical requirements of the SOO/SOW. If CVs for key personnel have been provided in the base contract, a one-paragraph biosketch will be sufficient for the task order response.

Volume 2 – Price Submission

The price submission should be clearly marked "**Volume 2, Price Submission, RTOR 0002**. To aide in the price submission evaluation, respondents are required to present their price information organized according to the following criteria.

f) The respondent shall include a price response substantially equivalent to the tables in Attachment 2.

g) The respondent shall include a price response per the Contract Line Item Number (CLIN) Structure shown in Table 1. The respondent shall submit a completed CLIN Structure (Table 1).

h) The response shall include the labor/pricing matrix(ces) for the base period and the option periods using the format included in Table 2 below. In Table 2 respondent shall list all labor categories proposed for each major Section of the SOO/SOW by WBS number and title as proposed by the respondent. The labor/pricing matrix(ces) should include labor categories as identified in the Master Contract Section J, the number of full time equivalents (FTEs), the number of total hours per labor category, and the total dollar value. The respondent shall include a comparison between the labor categories/hourly rates proposed in this task order to your Labor/Pricing Matrix(ces) in the Master contract (See attachment 7).

i) Price submissions must be in the WBS format. Those that do not match Table 2 will be returned to the Offeror for correction

j) The Offeror shall provide all labor categories and labor rates for work under the prospective contract. The hourly rates proposed for each labor category shall be fully burdened rates, including any indirect or overhead rates applicable. The fully burdened hourly rates will be incorporated into any resultant contract awards under SECTION B, Advance Understandings, and must be used for budgeting task orders and reimbursement of labor costs.

Table 1 – CLIN Structure

(1) BASE PERIODCOST REIMBURSEMENT CLIN

CLIN #	Description of Option Item(s) -or- Option Service(s)	Estimated Cost or Price
0001	Base Period – Clinical Study Services and Technical Reports on Task Orders.	

Table 2 – Labor/Price Matrix

WBS 1.0 – (WBS title) Labor/Price Matrix				
Labor Category	Estimated Hours	Standard Hourly Rate	OH(%) or any other cost associated with total labor	Total Price
		$		$
		$		$
		$		$
		$		$
Labor Subtotal				$
Materials Cost				$
Other Direct Costs				$
Fee ($/%)			%	$
Grand Total				$

Table 3- Cost Centers

Cost Center	Unit	Price per Unit	Total Units	Total Cost
Eg. Pathology Slides	Slide	$1/slide	1000	$1000

Material(s) Matrix

Materials Base Year	Base Year Cost	Materials Option Year 1	Estimated Option Year 1 Cost	Materials Option Year 2	Estimated Option Year 2 Cost
Grand Totals					

Attachment 2E – Task Order Administration Information

Task Order Administration Information in this section will be incorporated into the Task Order contract.

Contract Number:	(completed by the Task Order Level Contracting Officer (TOCO) at time of TO award)
Task Order Number:	(completed by the TOCO at time of TO award)
Tracking Number:	(completed by the TOCO at time of TO issuance)
Follow-on to Contract and Task Order Number:	(If this is a follow-on order insert the contract number and the TO number to which it is a follow-on. If this is not for a follow-on order, state "Not Applicable")
Task Order Level CO Name:	(completed by the TM or TOCO at time of TO issuance)
Organization:	HHS/ASPR /AMCG
Address:	330 Independence Ave., SW – Room G640 Washington, DC 20201
Phone Number:	(completed by the TM or TOCO at time of TO issuance)
Fax Number:	(completed by the TM or TOCO at time of TO issuance)
E-Mail Address:	(completed by the TM or TOCO at time of TO issuance)

1. Technical Monitors (TMs) will serve as immediate points of contact specifically related to the technical component of the task order.

a. Primary TM.

Name:	(completed by the TM or TOCO at time of TO issuance)
Organization:	BARDA
Address:	330 Independence Ave SW, Room G640, Washington DC 20201
Phone Number:	(completed by the TM or TOCO at time of TO issuance)
Fax Number:	(completed by the TM or TOCO at time of TO issuance)
E-Mail Address:	(completed by the TM or TOCO at time of TO issuance)

b. Alternate TM.

Name:	
Organization:	BARDA
Address:	330 Independence Ave SW, Room G640, Washington DC 20201
Phone Number:	
Fax Number:	
E-Mail Address:	

ATTACHMENT #3
DISCLOSURE OF LOBBYING ACTIVITIES, WITH INSTRUCTIONS

Please complete form available here:

http://www.whitehouse.gov/omb/grants/sflllin.pdf

ATTACHMENT #4
SMALL BUSINESS SUBCONTRACTING PLAN

If applicable, please complete form available here:

http://www.hhs.gov/about/smallbusiness/subcontractplan.html

ATTACHMENT #5

PROTECTION OF HUMAN SUBJECTS

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE NATIONAL INSTITUTES OF HEALTH **PROPOSAL SUMMARY AND DATA RECORD**	RFP/CONTRACT NUMBER

PROJECT TITLE (Title or RFP or Contract Proposal)

LEGAL NAME AND ADDRESS OF OFFEROR	PLACE OF PERFORMANCE (Full address including ZIP)

TYPE OF CONTRACT PROPOSED

☐ COST-REIMBURSEMENT ☐ FIXED PRICE ☐ COST-PLUS-FIXED-FEE ☐ OTHER

ESTIMATED TIME REQUIRED TO COMPLETE PROJECT

ESTIMATED DIRECT COSTS IN PROPOSED YEAR (From Budget	PROPOSED STARTING DATE

DOES THIS PROPOSAL INCLUDE A SUBCONTRACT ☐ YES ☐ NO (If yes, please furnish name and location of organization, description of services, basis for selection, responsible person employed by subcontractor and cost information.)

NAME AND TITLE OF PRINCIPAL INVESTIGATOR	SOCIAL SECURITY NO.	EST. HOURS WEEKLY	AREA CODE/TEL.NO.
NAME AND TITLE OF CO-INVESTIGATOR (Use attachment if necessary.)			

NAME AND TITLE OF INDIVIDUAL(S) AUTHORIZED TO NEGOTIATE CONTRACTS	AREA CODE/TELEPHONE NUMBER
NAME AND TITLE OF INDIVIDUAL(S) AUTHORIZED TO EXECUTE CONTRACTS	AREA CODE/TELEPHONE NUMBER

DOES THIS PROPOSAL INVOLVE EXPERIMENTS WITH HUMAN SUBJECTS ☐ YES ☐ NO

Institution's General Assurance re: Human Subjects DATE APPROVED _____ ☐ PENDING

Institution's Review Board's Approval of this Proposal DATE APPROVED _____ ☐ PENDING

An example of the informed consent for this study is enclosed ☐ YES ☐ NO

A Clinical Protocol is enclosed ☐ YES ☐ NO

OFFEROR'S ACKNOWLEDGMENT OF AMENDMENTS TO THE RFP (Use attachment if necessary)

ERRATA NUMBER	DATE	ERRATA NUMBER	DATE

NAME, ADDRESS, AND PHONE NUMBER OF COGNIZANT GOVERNMENT AUDIT AGENCY	NUMBER OF EMPLOYEES CURRENTLY EMPLOYED
	DOLLAR VOLUME OF BUSINESS PER ANNUM
	THIS OFFER EXPIRES _____ DAYS FROM THE DATE OF THIS OFFER (120 days if not specified)

FOR THE INSTITUTION

SIGNATURE OF PRINCIPAL INVESTIGATOR	SIGNATURE OF BUSINESS REPRESENTATIVE
TYPED NAME AND TITLE	TYPED NAME AND TITLE
EMPLOYER IDENTIFICATION NUMBER	DATE OF OFFER

Provision of the Social Security Number is voluntary. Social Security Numbers are requested for the purpose of accurate and efficient identification, review, and management of NIH Extramural Programs. Authority for requesting this information is provided by Title III, Section 301, and Title IV of the Public Health Service Act, as amended.

ATTACHMENT #6
OFFEROR'S POINTS OF CONTACT

Complete the following and return with the BUSINESS PROPOSAL.

Name, Title and Address* of Business Representative with whom daily contact is required

Name:	Telephone:
Title:	Fax:
Office:	E-Mail:
Organization:	
*Street Address:	
City, State, Zip Code:	

Name, Institutional Title and Address of Proposed Principal

Name:	Telephone:
Title:	Fax:
Office:	E-Mail:
Organization:	
*Street Address:	
City, State, Zip Code:	

These exact addresses are necessary to ensure that contact can be made with the proper individual(s) in the most expeditious manner.

*****Please use actual street address, not P.O. Box.

ATTACHMENT #7

INVOICE/FINANCING REQUEST INSTRUCTIONS - FOR COST-REIMBURSEMENT TYPE CONTRACTS

Format: Payment requests shall be submitted on the Contractor's self-generated form in the manner and format prescribed herein and as illustrated in the Sample Invoice/Financing Request. Standard Form 1034, Public Voucher for Purchases and Services Other Than Personal, may be used in lieu of the Contractor's self-generated form provided it contains all of the information shown on the Sample Invoice/Financing Request. DO NOT include a cover letter with the payment request.

Number of Copies: Payment requests shall be submitted in the quantity specified in the Invoice Submission Instructions in Section G of the Contract Schedule.

Frequency: Payment requests shall not be submitted more frequently than once every two weeks in accordance with the Allowable Cost and Payment Clause incorporated into this contract. Small business concerns may submit invoices/financing requests more frequently than every two weeks when authorized by the Contracting Officer.

Cost Incurrence Period: Costs incurred must be within the contract performance period or covered by pre-contract cost provisions.

Billing of Costs Incurred: If billed costs include (1) costs of a prior billing period, but not previously billed, or (2) costs incurred during the contract period and claimed after the contract period has expired, the Contractor shall site the amount(s) and month(s) in which it incurred such costs.

Contractor's Fiscal Year: Payment requests shall be prepared in such a manner that the Government can identify costs claimed with the Contractor's fiscal year.

Currency: All BARDA contracts are expressed in United States dollars. When the Government pays in a currency other than United States dollars, billings shall be expressed, and payment by the Government shall be made, in that other currency at amounts coincident with actual costs incurred. Currency fluctuations may not be a basis of gain or loss to the Contractor. Notwithstanding the above, the total of all invoices paid under this contract may not exceed the United States dollars authorized.

Costs Requiring Prior Approval: Costs requiring the Contracting Officer's approval, including those set forth in an Advance Understanding in the contract, shall be identified and reference the Contracting Officer's Authorization (COA) Number. In addition, the Contractor shall show any cost set forth in an Advance Understanding as a separate line item on the payment request.

Invoice/Financing Request Identification: Each payment request shall be identified as either:

(a) **Interim Invoice/Contract Financing Request:** These are interim payment requests submitted during the contract performance period.

(b) **Completion Invoice:** The completion invoice shall be submitted promptly upon completion of the work, but no later than one year from the contract completion date, or within 120 days after settlement of the final indirect cost rates covering the year in which the contract is physically complete

(whichever date is later). The Contractor shall submit the completion invoice when all costs have been assigned to the contract and it completes all performance provisions.

(c) **Final Invoice:** A final invoice may be required after the amounts owed have been settled between the Government and the Contractor (e.g., resolution of all suspensions and audit exceptions).

Preparation and Itemization of the Invoice/Financing Request: The Contractor shall furnish the information set forth in the instructions below. The instructions are keyed to the entries on the Sample Invoice/Financing Request.

(a) **Designated Billing Office Name and Address:** Enter the designated billing office name and address, as identified in the Invoice Submission Instructions in Section G of the Contract Schedule.

(b) **Contractor's Name, Address, Point of Contact, VIN, and DUNS or DUNS+4 Number:** Show the Contractor's name and address exactly as they appear in the contract, along with the name, title, phone number, and e-mail address of the person to notify in the event of an improper invoice or, in the case of payment by method other than Electronic Funds Transfer, to whom payment is to be sent. Provide the Contractor's Vendor Identification Number (VIN), and Data Universal Numbering System (DUNS) number or DUNS+4. The DUNS number must identify the Contractor's name and address exactly as stated on the face page of the contract. When an approved assignment has been made by the Contractor, or a different payee has been designated, provide the same information for the payee as is required for the Contractor (i.e., name, address, point of contact, VIN, and DUNS).

(c) **Invoice/Financing Request Number:** Insert the appropriate serial number of the payment request.

(d) **Date Invoice/Financing Request Prepared:** Insert the date the payment request is prepared.

(e) **Contract Number and Order Number (if applicable):** Insert the contract number and order number (if applicable).

(f) **Effective Date:** Insert the effective date of the contract or if billing under an order, the effective date of the order.

(g) **Total Estimated Cost of Contract/Order:** Insert the total estimated cost of the contract, exclusive of fixed-fee. If billing under an order, insert the total estimated cost of the order, exclusive of fixed-fee. For incrementally funded contracts/orders, enter the amount currently obligated and available for payment.

(h) **Total Fixed-Fee:** Insert the total fixed-fee (where applicable) or the portion of the fixed-fee applicable to a particular invoice as defined in the contract.

(i) **Two-Way/Three-Way Match:** Identify whether payment is to be made using a two-way or three-way match. To determine required payment method, refer to the Invoice Submission Instructions in Section G of the Contract Schedule.

(j) **Office of Acquisitions:** Insert the name of the Office of Acquisitions, as identified in the Invoice Submission Instructions in Section G of the Contract Schedule.

(k) **Central Point of Distribution:** Insert the Central Point of Distribution, as identified in the Invoice Submission Instructions in Section G of the Contract Schedule.

(l) **Billing Period:** Insert the beginning and ending dates (month, day, and year) of the period in which costs were incurred and for which reimbursement is claimed.

(m) **Amount Billed - Current Period:** Insert the amount claimed for the current billing period by major cost element, including any adjustments and fixed-fee. If the Contract Schedule contains separately priced line items, identify the contract line item(s) on the payment request and include a separate breakdown (by major cost element) for each line item.

(n) **Amount Billed - Cumulative:** Insert the cumulative amounts claimed by major cost element, including any adjustments and fixed-fee. If the Contract Schedule contains separately priced line items, identify the contract line item(s) on the payment request and include a separate breakdown (by major cost element) for each line item.

(o) **Direct Costs:** Insert the major cost elements. For each element, consider the application of the paragraph entitled "Costs Requiring Prior Approval" on page 1 of these instructions.

(1) **Direct Labor:** Include salaries and wages paid (or accrued) for direct performance of the contract. List individuals by name, title/position, hourly/annual rate, level of effort (actual hours or % of effort), breakdown by task performed by personnel, and amount claimed.

(2) **Fringe Benefits:** List any fringe benefits applicable to direct labor and billed as a direct cost. Do not include in this category fringe benefits that are included in indirect costs.

(3) **Accountable Personal Property:** Include any property having a unit acquisition cost of $5,000 or more, with a life expectancy of more than two years, and sensitive property regardless of cost (see the HHS *Contractor's Guide for Control of Government Property*)(e.g. personal computers). Note this is not permitted for reimbursement without pre-authorization from the CO.

On a separate sheet of paper attached to the payment request, list each item for which reimbursement is requested. Include reference to the following (as applicable):

- item number for the specific piece of equipment listed in the Property Schedule, and

- COA number, if the equipment is not covered by the Property Schedule.

The Contracting Officer may require the Contractor to provide further itemization of property having specific limitations set forth in the contract.

(4) **Materials and Supplies:** Include all consumable material and supplies regardless of amount. Detailed line-item breakdown (e.g. receipts, quotes, etc.) is required.

(5) **Premium Pay:** List remuneration in excess of the basic hourly rate.

(6) **Consultant Fee:** List fees paid to consultants. Identify consultant by name or category as set forth in the contract or COA, as well as the effort (i.e., number of hours, days, etc.) and rate billed.

(7) **Travel:** Include domestic and foreign travel. Foreign travel is travel outside of Canada, the United States and its territories and possessions. However, for an organization located outside

Canada, the United States and its territories and possessions, foreign travel means travel outside that country. Foreign travel must be billed separately from domestic travel.

(8) **Subcontract Costs:** List subcontractor(s) by name and amount billed. Provide subcontract invoices/receipts as backup documentation. If subcontract is of the cost-reimbursement variety, detailed breakdown will be required. Regardless, include backup documentation (e.g. subcontractor invoices, quotes, etc.).

(9) **Other:** Include all other direct costs not fitting into an aforementioned category. If over $1,000, list cost elements and dollar amounts separately. If the contract contains restrictions on any cost element, that cost element must be listed separately.

(p) **Cost of Money (COM):** Cite the COM factor and base in effect during the time the cost was incurred and for which reimbursement is claimed, if applicable.

(q) **Indirect Costs:** Identify the indirect cost base (IDC), indirect cost rate, and amount billed for each indirect cost category.

(r) **Fixed-Fee:** Cite the formula or method of computation for fixed-fee, if applicable. The fixed-fee must be claimed as provided for by the contract.

(s) **Total Amounts Claimed:** Insert the total amounts claimed for the current and cumulative periods.

(t) **Adjustments:** Include amounts conceded by the Contractor, outstanding suspensions, and/or disapprovals subject to appeal.

(u) **Grand Totals**

(v) **Certification of Salary Rate Limitation:** If required by the contract (see Invoice Submission Instructions in Section G of the Contract Schedule), the Contractor shall include the following certification at the bottom of the payment request:

"I hereby certify that the salaries billed in this payment request are in compliance with the Salary Rate Limitation Provisions in Section H of the contract."

**Note the Contracting Officer may require the Contractor to submit detailed support for costs claimed on payment requests. Every cost must be determined to be allocable, reasonable, and allowable per FAR Part 31.

ATTACHMENT #8

INVOICE/FINANCING REQUEST INSTRUCTIONS FOR FIXED PRICE TYPE CONTRACTS

General The Offeror shall submit vouchers or invoices as prescribed herein.

Format Standard Form l034, Public Voucher for Purchases and Services Other Than Personal, and Standard Form l035, Public Voucher for Purchases and Services Other than Personal--Continuation Sheet, and the payee's letterhead or self-designed form should be used to submit claims for reimbursement.

Number of Copies: As indicated in the contract.

Frequency Invoices submitted in accordance with the Payment Clause shall be submitted monthly upon delivery of goods or services unless otherwise authorized by the Contracting Officer.

Preparation and Itemization of the Invoice The invoice shall be prepared as follows:

(a) Designated Billing Office and address:

HHS/ASPR/BARDA

330 Independence Ave, Room G644

Washington DC 20201

ATTN: Contracting Officer

(b) Invoice Number

(c) Date of Invoice

(d) Contract number and date

(e) Payee's name and address. Show the Offeror's name (as it appears in the contract), correct address, and the title and phone number of the responsible official to whom payment is to be sent. When an approved assignment has been made by the Offeror, or a different payee has been designated, then insert the name and address of the payee instead of the Offeror.

(f) Description of goods or services, quantity, unit price, (where appropriate), and total amount.

(g) Charges for freight or express shipments other than F.O.B. destination. (If shipped by freight or express and charges are more than $25, attach prepaid bill.)

(h) Equipment - If there is a contract clause authorizing the purchase of any item of equipment, the final invoice must contain a statement indicating that no item of equipment was purchased or include a completed form HHS-565, Report of Capitalized Nonexpendable Equipment.

Currency: Where payments are made in a currency other than United States dollars, billings on the contract shall be expressed, and payment by the United States Government shall be made, in that other currency at amounts coincident with actual costs incurred. Currency fluctuations may not be a basis of gain or loss to the Offeror. Notwithstanding the above, the total of all invoices paid under this contract may not exceed the United States dollars authorized.

ATTACHMENT #9

RISK MITIGATION PLAN / MATRIX TEMPLATE

Offeror's Name Risk Mitigation Matrix (RMM) Risks identified from XXXX (Contract number or specific document) Date											
Prior to Risk Mitigations Strategy						Post Risk Mitigations Strategy					
Risks	Probability of Occurrence	Risk to project (Severity)	Risk to Cost	Risk to Schedule	Risk to Tech Performance	Risk Mitigation effort	Probability of Occurrence	Risk to project (Severity)	Risk to Cost	Risk to schedule	Risk to Tech Performance

ATTACHMENT #10

CONTRACT PERFORMANCE EVALUATION REPORT

Evaluation Type: Interim __ Final __ (*check one)*		
Evaluating Organization:	**Reporting Period: From to**	
Contracting Office:	**Contract Number:**	**Order Number:**

Contractor Name:	**Contractor Address:**	
DUNS:	**City:**	**State:**
Additional or Alternate Contractor Name:	**Zip/Postal Code:**	**Country:**

TIN:	**Industrial Code (NAICS):**	**Commodity Code:**	**Contract Type:**

Contract Award Date:	**Contract Expiration Date:**	**Contract Value:**

Requirement Description:

Ratings

Summarize contractor performance and check the number which corresponds to the rating for each rating category (*See attached Rating Guidelines).*

Quality of Product or Service

_0=Unsatisfactory _1=Poor _2=Fair _3=Good _4=Excellent _5=Outstanding

Government Comments for Quality of Product or Service (2000 characters maximum):

Cost Control (*Rating and Comments for Cost Control <u>are not</u> required if contract type is Fixed-Price)*

_0=Unsatisfactory _1=Poor _2=Fair _3=Good _4=Excellent _5=Outstanding

Government Comments for Cost Control (2000 characters maximum):

Timeliness of Performance

_0=Unsatisfactory _1=Poor _2=Fair _3=Good _4=Excellent _5=Outstanding

Government Comments for Timeliness of Performance (2000 characters maximum):

Business Relations

_0=Unsatisfactory _1=Poor _2=Fair _3=Good _4=Excellent _5=Outstanding

Government Comments for Business Relations (2000 characters maximum):

Additional Info

Subcontracts

Are subcontracts involved? __Yes __No (*Check one)*
Government Comment on subcontracts (2000 characters maximum):

Contractor Key Personnel

Contractor Manager/Principal Investigator (*name):*
Government Comment on Contractor Manager/Principal Investigator (2000 characters maximum):

Contractor Key Person (*name):*
Government Comment on Contractor Key Person (2000 characters maximum):

Contractor Key Person (*name):*
Government Comment on Contractor Key Person (2000 characters maximum):

Small Business Subcontracting Plan

Did the contractor make a good faith effort to comply with its subcontracting plan consistent with the goals and objectives, reporting and other aspects of the plan? _Yes _No _N/A (*Check one)*

If this is a bundled contract, did the contractor meet the goals and objectives for small business participation? _Yes _No _N/A (*Check one)*

Government Comments on Small Business Subcontracting Plan (2000 characters maximum):

Small Disadvantaged Business Goals

Did the contractor make a good faith effort to comply with its subcontracting plan consistent with the goals and objectives, for small disadvantaged business (SDB) participation, monetary targets for SDB participation, and required notifications? _Yes _No _N/A (*Check one)*

Government Comments on Small Disadvantaged Business Goals (2000 characters maximum):

Customer Satisfaction

Is/was the contractor committed to customer satisfaction? **_Yes** **_No (*Check one)***

Would you recommend the selection of this firm again? **_Yes** **_No (*Check one)* – *FINAL REPORT ONLY***

Government Comments on Customer Satisfaction (2000 characters maximum):

Admin Info

Project Officer/COR
Name:
Phone:
Fax:
E-mail Address:

Contractor Representative
Name:
Phone:
Fax:
E-mail Address:

Alternate Contractor Representative (*Required to insure that at least one person is notified of evaluation)*
Name:
Phone:
Fax:
E-mail Address:

Contracting Officer:
Name:
Phone:
Fax:
E-mail Address:

Contractor Comments

Quality of Product of Service

___Contractor has elected not to comment

Contractor Comments for Quality of Product of Service (2000 characters maximum):

Cost Control

___Contractor has elected not to comment

Contractor Comments for Quality of Product of Service (2000 characters maximum):

Timeliness of Performance

___Contractor has elected not to comment

Contractor Comments for Timeliness of Performance (2000 characters maximum):

Business Relations

___Contractor has elected not to comment

Contractor Comments for Business Relations (2000 characters maximum):

Overall Comment

___Contractor has elected not to comment

Contractor Comments for Quality of Product of Service (2000 characters maximum):

Rating Guidelines

Quality of Product or Service

0 = Unsatisfactory 1 = Poor 2 = Fair 3 = Good 4 = Excellent 5 = Outstanding

Unsatisfactory	Non-conformances are jeopardizing the achievement of contract requirements, despite use of Agency resources. Recovery is not likely. If performance cannot be substantially corrected, it constitutes a significant impediment in consideration for future awards containing similar requirements.
Poor	Overall compliance requires significant Agency resources to ensure achievement of contract requirements.
Fair	Overall compliance requires minor Agency resources to ensure achievement of contract requirements.
Good	There are no, or very minimal, quality problems, and the Contractor has met the contract requirements.
Excellent	There are no quality issues, and the Contractor has substantially exceeded the contract performance requirements without commensurate additional costs to the Government.
Outstanding	The contractor has demonstrated an outstanding performance level that was significantly in excess of anticipated achievements and is commendable as an example for others, so that it justifies adding a point to the score. It is expected that this rating will be used in those rare circumstances where contractor performance clearly exceeds the performance levels described as "Excellent".

Cost Control

0 = Unsatisfactory 1 = Poor 2 = Fair 3 = Good 4 = Excellent 5 = Outstanding

Unsatisfactory	Ability to manage cost issues is jeopardizing performance of contract requirements, despite use of Agency resources. Recovery is not likely. If performance cannot be substantially corrected, this level of ability to manage cost issues constitutes a significant impediment in consideration for future awards.
Poor	Ability to manage cost issues requires significant Agency resources to ensure achievement of contract requirements.
Fair	Ability to control cost issues requires minor Agency resources to ensure achievement of contract requirements.
Good	There are no, or very minimal, cost management issues and the Contractor has met the contract requirements.
Excellent	There are no cost management issues and the Contractor has exceeded the contract requirements, achieving cost savings to the Government.
Outstanding	The contractor has demonstrated an outstanding performance level that justifies adding a point to the score. It is expected that this rating will be used in those rare circumstances where the contractor achieved cost savings and performance clearly exceeds the performance levels described as "Excellent".

Timeliness of Performance

0 = Unsatisfactory 1 = Poor 2 = Fair 3 = Good 4 = Excellent 5 = Outstanding

Unsatisfactory	Delays are jeopardizing the achievement of contract requirements, despite use of Agency resources. Recovery is not likely. If performance cannot be substantially corrected, it constitutes a significant impediment in consideration for future awards.
Poor	Delays require significant Agency resources to ensure achievement of contract requirements.
Fair	Delays require minor Agency resources to ensure achievement of contract requirements.
Good	There are no, or minimal, delays that impact achievement of contract requirements.
Excellent	There are no delays and the contractor has exceeded the agreed upon time schedule.
Outstanding	The contractor has demonstrated an outstanding performance level that justifies adding a point to the score. It is expected that this rating will be used in those rare circumstances where contractor performance clearly exceeds the performance levels described as "Excellent".

Business Relations

0 = Unsatisfactory 1 = Poor 2 = Fair 3 = Good 4 = Excellent 5 = Outstanding

Unsatisfactory	Response to inquiries and/or technical, service, administrative issues is not effective. If not substantially mitigated or corrected it should constitute a significant impediment in considerations for future awards.
Poor	Response to inquiries and/or technical, service, administrative issues is marginally effective.
Fair	Response to inquiries and/or technical, service, administrative issues is somewhat effective.
Good	Response to inquiries and/or technical, service, administrative issues is consistently effective.
Excellent	Response to inquiries and/or technical, service, administrative issues exceeds Government expectation.
Outstanding	The contractor has demonstrated an outstanding performance level that justifies adding a point to the score. It is expected that this rating will be used in those rare circumstances where contractor performance clearly exceeds the performance levels described as "Excellent".

ATTACHMENT #11
PAST PERFORMANCE QUESTIONNAIRE

Please complete the following questionnaire and return via regular fax to the attention of:

Jason Bell, CONTRACTING OFFICER by **no later than May 16, 2013.**
(Name) (Title) (Date)

330 INDEPENDENCE AVENUE, SW, ROOM G640, WASHINGTON, DC 20201
(Address)

202/260-1457 jason.bell@hhs.gov
(Fax Number) (Email)
This survey pertains to: **(VENDOR NAME)**
Department/Component: _____
Contract Number: _____
Date of Survey: _____
Name of Person Completing Survey: _____
Signature of Person Completing Survey: _____
Your Company/Agency: _____
Your Role in this Contract *(circle one)*:
Contracting Officer Contract Specialist Project Officer Other _____
Contract Value *(including options)*: $_____
Performance Period: _____
(including option periods)
Type of Contract: _____
Approximate percentage of work being performed (or completed) by subcontractor(s): _____%
Information on subcontractor(s) *(where more than ____% of work was completed by the subcontractor)*:

_____ _____
Subcontractor Program Manager Phone

_____ _____
Subcontractor Program Manager Phone
General description of products/services required _____
under the contract:

RATINGS

Please answer each of the following questions with a rating that is based on objective measurable performance indicators to the maximum extent possible. Commentary to support rating may be noted at the end of the questionnaire under 'additional comments'.
Assign each area a rating of 0 (Unsatisfactory), 1 (Poor), 2 (Fair), 3 (Good), 4 (Excellent) or 5 (Outstanding). Use the attached Rating Guidelines as guidance in making these evaluations. Circle the appropriate rating. If you do not have enough personal knowledge or feedback from internal customers who directly received products and services
from the Contractor to make a determination on any of the performance criteria below, please circle "N/A" (not applicable /no opinion).

QUALITY OF SERVICE

1. Compliance with contract requirements
0 1 2 3 4 5 N/A
2. Accuracy of reports
0 1 2 3 4 5 N/A
3. Effectiveness of personnel
0 1 2 3 4 5 N/A
4. Technical excellence
0 1 2 3 4 5 N/A

COST CONTROL

1. Record of forecasting and controlling target costs
0 1 2 3 4 5 N/A
2. Current, accurate and complete billings
0 1 2 3 4 5 N/A
3. Relationship of negotiated costs to actuals
0 1 2 3 4 5 N/A
4. Cost efficiencies
0 1 2 3 4 5 N/A

TIMELINESS OF PERFORMANCE

1. Met interim milestones
0 1 2 3 4 5 N/A
2. Reliability
0 1 2 3 4 5 N/A
3. Responsive to technical direction
0 1 2 3 4 5 N/A
4. Completed on time including wrap-up and contract administration
0 1 2 3 4 5 N/A
5. Met delivery schedules
0 1 2 3 4 5 N/A
6. Liquidated damages assessed: Yes No *(circle one)*

BUSINESS RELATIONS

1. Effective management, including subcontracts
0 1 2 3 4 5 N/A
2. Reasonable/cooperative behavior
0 1 2 3 4 5 N/A
3. Responsive to contract requirements
0 1 2 3 4 5 N/A
4. Notification of problems
0 1 2 3 4 5 N/A
5. Flexibility
0 1 2 3 4 5 N/A
6. Pro-active vs. reactive
0 1 2 3 4 5 N/A
7. Effective small/small disadvantaged business subcontracting program
0 1 2 3 4 5 N/A

CUSTOMER SATISFACTION

1. The Contractor is committed to customer satisfaction.

Yes No *(circle one)*

2. Would you recommend selection of this firm again?

Yes No *(circle one)*

ADDITIONAL COMMENTS

RATING GUIDELINES QUALITY OF PRODUCT OR SERVICE	COST CONTROL	TIMELINESS OF PERFORMANCE	BUSINESS RELATIONS
0 – Unsatisfactory	Contractor is not in compliance and is jeopardizing achievement of contract objectives	Contractor is unable to manage costs effectively	Contractor delays are jeopardizing performance of contract objectives	Response to inquiries, technical/service/ administrative issues is not effective
1 – Poor	Major problems have been encountered	Contractor is having major difficulty in managing costs effectively	Contractor is having major difficulty meeting milestones and delivery schedules	Response to inquiries, technical/service/ administrative issues is marginally effective
2 – Fair	Some problems have been encountered	Contractor is having some problems in managing costs effectively	Contractor is having some problems meeting milestones and delivery schedules	Response to inquiries, technical/service/ administrative issues is somewhat effective
3 – Good	Minor inefficiencies/errors have been identified	Contractor is usually effective in managing costs	Contractor is usually effective in meeting milestones and delivery schedules	Response to inquiries, technical/service/ administrative issues is usually effective
4 – Excellent	Contractor is in compliance with contract requirements and/or delivers quality products/services	Contractor is effective in managing costs and submits current, accurate and complete billings	Contractor is effective in meeting milestones and delivery schedules	Response to inquiries, technical/service/ administrative issues is effective
5 – Outstanding: The Contractor has demonstrated an outstanding performance level in any of the above four categories that justifies adding a point to the score. It is expected that this rating will be used in those rare circumstances when Contractor performance clearly exceeds the performance levels described as “Excellent”.			

ATTACHMENT #12

SUMMARY OF RELATED ACTIVITIES

The following specific information must be provided by the Offeror pertaining to the Project Director, Principal Investigator, and each of any other proposed key professional individuals designated for performance under any resulting contract.

a. Identify the total amount of all presently active federal contracts/cooperative agreements/grants and commercial agreements citing the committed levels of effort for those projects for each of the key individuals***** in this proposal.

Professional's Name and Title/Position:

Identifying Number	Agency	Total Effort Committed
1.		
2.		
3.		
4.		

*****If an individual has no obligation(s), so state.

b. Provide the total number of outstanding proposals, exclusive of the instant proposal, having been submitted by your organization, not presently accepted but in an anticipatory stage, which will commit levels of effort by the proposed professional individuals*****.

Professional's Name and Title/Position:

Identifying Number	Agency	Total Effort Committed
1.		
2.		
3.		
4.		

*****If no commitment of effort is intended, so state.

c. Provide a statement of the level of effort to be dedicated to any resultant contract awarded to your organization for those individuals designated and cited in this proposal.

Name	Title/Position	Total Proposed Effort
1.		
2.		
3.		
4.		

ATTACHMENT #13

ACH VENDOR / MISCELLANEOUS PAYMENT ENROLLMENT FORM

Payment Information Form

The information requested on this form concerns your financial institution, your account at that institution, and personal information which needs to verified and completed.

Privacy Act Statement

The following information is provided to comply with the Privacy Act of 1974 (P.L. 93-579). All information collected on this form is required under the provisions of 31 USC 3322 and 31 CFR 210. This information will be used by the Treasury Department to transmit payment data, by electronic means to your financial institution. Failure to provide the requested information may delay or prevent the receipt of payments through the Automated Clearing House Payment System.

Check one of the following:

☐ Federal Employee: ☐ Contractor: ☐ Vendor:

Name: _____

Business Address: _____

_____

Remit To
(If same as above, leave blank. Must match address on invoice for internal control purposes.)
Address: _____

_____

Taxpayer Identification # (TIN): ___ ___ ___ ___ ___ ___ ___ ___ ___
(If you are an individual, this may be your Social Security number)

1. Payee's Telephone Number: (_____) _____

The following information must be completed by your financial institution representative:	

2. Name of Financial Institution:
_____

3. Address of Financial Institution:

_____

_____

_____

4. Financial Institution's 9-digit ABA Routing Number for

Transfer of Funds: ___ ___ ___ ___ ___ ___ ___ ___ ___

5. Depositor Account Title: _____

6. Depositor Account Number:														

7. Type of Account: ☐ Checking ☐ Savings

8. Signature and Title of Authorized Official of Financial Institution:

_____

Telephone Number: (_____) _____ Date: _____

********** The following must be signed by the payee**********

I have verified the information on this form.

_____ _____
Signature Date